

# Exhibit B

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IN RE: PELVIC MESH/GYNECARE :  
2 LITIGATION :

3 PATRICIA L. HAMMONS, :COURT OF COMMON PLEAS  
:PHILADELPHIA COUNTY  
4 Plaintiff, :MAY TERM, 2013  
vs. :  
5 :  
ETHICON, INC., et al., :  
6 :  
Defendants. :No. 003913

7 -----  
8  
9 November 21, 2015  
10  
11

12 Oral sworn videotaped de bene esse  
13 at deposition of DANIEL S. ELLIOTT, M.D.,  
14 held MAZIE SLATER KATZ & FREEMAN, LLC, 103  
15 Eisenhower Parkway, 2nd Floor, Roseland, New  
16 Jersey, before Margaret M. Reihl, RPR, CCR,  
17 CRR, CLR and Notary Public, on the above date,  
18 commencing at 9:20 a.m.  
19  
20  
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Daniel S. Elliott, M.D.

1 THE VIDEOGRAPHER: All right. We are now  
2 on the record. My name is Thomas Keighley, and  
3 I am a videographer for Golkow Technologies.  
4 Today's date is November 21st, 2015. The time  
5 is approximately 9:20 a.m. This video  
6 deposition is being held in Roseland, New  
7 Jersey at 103 Eisenhower Parkway at the offices  
8 of Mazie Slater Katz & Freeman. We are here in  
9 the matter of Pelvic Mesh, specifically Hammons  
10 versus Ethicon, Inc., et al. This is for the  
11 Court of Common Pleas, Lehigh County. The  
12 deponent is Dr. Daniel Elliott.

13 Counsel, your appearances will be noted on  
14 the stenographic record, and the court reporter  
15 is Peg Reihl, if she could swear in the witness  
16 and we can proceed.

17 ... DANIEL S. ELLIOTT, M.D., having been  
18 duly sworn as a witness, was examined and  
19 testified as follows ...

20 MR. ISMAIL: Just if I can note for the  
21 stenographic record, I guess now for the video  
22 as well, there was a cross-notice filed for  
23 this notice -- of this deposition in the MDL to  
24 which Ethicon filed a motion to quash. That

1 motion is still pending. I just want to make  
2 sure that objection was preserved and noted on  
3 this record.

4 MR. SLATER: My understanding is just from  
5 seeing some correspondence that the plaintiffs  
6 maintained their cross-notice, and I guess that  
7 will be decided by the federal judges.

8 MR. ISMAIL: Yes, thank you.

9 BY MR. SLATER:

10 Q. You can look at me when you speak,  
11 Dr. Elliott. It's actually fine either way, okay?

12 A. Okay.

13 MR. SLATER: Are we ready to proceed? Did  
14 you swear the witness? You swore him in?  
15 Okay, great. Okay. Let's proceed.

16 - - -

17 DIRECT EXAMINATION

18 - - -

19 BY MR. SLATER:

20 Q. Good morning, Dr. Elliott.

21 A. Good morning.

22 Q. Dr. Elliott, we've marked for  
23 identification a document P2239. Can you tell us what  
24 that document is?



1 A. This is my current Curriculum Vitae.

2 Q. That's a list of your background, your  
3 education, your qualifications, that type of thing?

4 A. That's correct.

5 Q. Would you tell the jury what your  
6 profession is, please.

7 A. I am a urologic reconstructive surgeon at  
8 the Mayo Clinic.

9 Q. And tell the jury where you're a licensed  
10 physician.

11 A. In the state of Minnesota.

12 Q. What is the Mayo Clinic where you work?

13 A. It's a large tertiary care medical center,  
14 meaning -- tertiary care just means the end of the line  
15 type thing, you don't get referred on from there, which  
16 is a multi-specialty practice.

17 Q. And where is that located?

18 A. In Rochester, Minnesota.

19 Q. Tell the jury a little bit about your  
20 educational background, where you went to medical  
21 school, your residency, the training you did from that  
22 point forward briefly.

23 A. Medical school was in southern California  
24 at Loma Linda University School of Medicine. Then I

1 did a one-year general surgery at the Mayo Clinic in  
2 Rochester, Minnesota, followed by five years of  
3 urologic surgery training at Mayo Clinic. I was asked  
4 to come on staff and then did a one-year advanced  
5 surgical fellowship at the Baylor College of Medicine  
6 in Houston.

7 Q. Would you tell the jury about your medical  
8 practice, what you do day to day?

9 A. It's the reconstructive urology means  
10 we're taking care of problems that are occurring in the  
11 pelvis, complications dealing with males and females.  
12 Majority of my practice, probably roughly two-thirds is  
13 female, one-third is male.

14 Q. What are the types of conditions you  
15 treat?

16 A. Breaking down into stress incontinence,  
17 both male and female, pelvic organ prolapse for females  
18 and then the complications arising from those  
19 treatments.

20 Q. Do you teach, do you have any teaching  
21 appointments?

22 A. Yes. I'm a teacher at Mayo as far as  
23 teaching residents, rotations on my service, lectures  
24 for medical students. Also, I guess you could call it

1 an educator with the SUFU, which is Society of  
2 Urodynamics & Female Urology, I'm on the education --

3 Q. Say that a little slower. What is SUFU?

4 A. Society of Urodynamics & Female Urology,  
5 that's the large, arguably the most elite in the United  
6 States society dealing with female urology and pelvic  
7 floor function, and so I'm on the education committee  
8 for that. So that there's education as far as future  
9 education for both residents, though, mainly for  
10 individuals who have already graduated and are in  
11 practice.

12 Q. As part of your training and teaching of  
13 residents, do you have occasion to teach with regard to  
14 IFUs, the instructions for use for medical devices?

15 A. It would be on a daily basis with  
16 residents, especially new residents who are coming on  
17 my service, we go over the IFUs, if we're using a  
18 medical device, and then if there's a new product that  
19 comes out, we'll review those.

20 Q. When you teach residents about the IFU,  
21 what are the types of things you focus on when you're  
22 actually teaching day-to-day?

23 A. Well, we go over everything. It depends  
24 upon if it's a new resident or not. Let's take a new

1 resident, typical one, it's every six weeks I have a  
2 new resident on my service. We sit down, we go over  
3 the IFU, we go over the procedure, how it's described  
4 and then the various different warnings or potential  
5 complications.

6 Q. As part of that process, have you learned  
7 what it is that you're looking for in an IFU and what  
8 needs to be taught to physicians to look for?

9 A. Oh, absolutely, but that's not just with  
10 IFUs. That's also as far as paper writing and  
11 reviewing of manuscripts.

12 Q. Do you have involvement with the  
13 peer-reviewed literature?

14 A. Yes.

15 Q. Tell the jury your involvement -- first of  
16 all, what is the peer-reviewed medical literature?

17 A. Peer reviewed for any article coming out  
18 in a reputable journal, it will be reviewed by multiple  
19 individuals within your peer group, so that's why it's  
20 peer reviewed. So I'm a reviewer for some 16 different  
21 journals, more or less, and so your responsibility is  
22 to obtain a manuscript, look at it critically. The  
23 goal is to find weaknesses in the paper, strengths in  
24 the paper, what is lacking, where it can be improved.

1 Q. Do you act as a peer reviewer?

2 A. Yes, for I say roughly 16 journals.

3 Q. Have you published articles in the  
4 peer-reviewed medical literature yourself?

5 A. Yes, I have.

6 Q. Do you have experience treating prolapse  
7 with mesh?

8 A. Yes.

9 Q. Tell the jury that experience.

10 A. Surgically treating prolapse is dealing  
11 with only transabdominal or robotic. I have never  
12 placed transvaginal mesh for prolapse.

13 Q. Do you perform procedures to treat  
14 prolapse that do not involve mesh?

15 A. Yes.

16 Q. Tell the jury about that.

17 A. Well, there's going to be a spectrum of  
18 different conditions, bladder, rectum or enterocele  
19 where the intestines fall down, and I have been trained  
20 and daily or every other day perform transvaginal  
21 prolapse repairs, but not with mesh.

22 Q. What do you use to do those procedures?

23 A. It's the traditional colporrhaphy is the  
24 name of it using sutures, absorbable sutures.

1 Q. Have you attended at any point training  
2 with regard to mesh kits like the Prolift®?

3 A. Yes.

4 Q. Tell us about that.

5 A. It was with AMS, I was an instructor, they  
6 had combined incontinence and prolapse. I taught the  
7 incontinence part, but also the cadavers right next to  
8 me were where the instructors were teaching the  
9 transvaginal prolapse repair, so I went over and then  
10 did that with those instructors.

11 Q. And that was for the AMS Apogee and  
12 Perigee?

13 A. Correct.

14 Q. Is that a similar product to the Prolift®?

15 A. Very similar, yes.

16 Q. Over the years have you become involved in  
17 treating patients who had Prolifts® placed by other  
18 doctors at other locations where they've had  
19 complications?

20 A. Correct, yes, I have.

21 Q. Tell us about your treatment of women with  
22 Prolift® complications or other mesh complications as  
23 well.

24 A. That began roughly 2006, 2007, in that

1 time frame, I don't remember the exact time, but that  
2 was the ballpark that we started seeing various  
3 different complications like vaginal extrusion, organ  
4 erosion and more commonly pelvic pain.

5 Q. In your practice, have you treated  
6 patients who have had complications from the Prolift®?

7 A. Yes.

8 Q. And is that what you were just describing?  
9 Is that among the patients that you've treated with  
10 those conditions?

11 A. Correct.

12 Q. As part of your treatment of patients with  
13 Prolift® complications, did you become familiar with  
14 the Prolift® system?

15 A. Yes.

16 Q. What did you do?

17 A. Well, initially, besides just when these  
18 complications would come in, you know, I'm attending  
19 meetings, national, international meetings, we would be  
20 discussing it with colleagues in the field,  
21 urogynecology colleagues, my institution. We would go  
22 back online and look at the product, because, remember,  
23 I chose not to place the product, so we had to learn  
24 about how is this put in, reviewing of manuscripts. We

1 always do that, a PubMed search, which is the largest  
2 search engine looking for articles about this and  
3 management of complications.

4 Q. Did you have the opportunity to see the  
5 IFU at some point as part of your practice as well?

6 A. Yes, with the Prolift®, yes.

7 Q. Was it helpful to you in treating the  
8 complications to learn about the Prolift® system?

9 A. From the IFU?

10 Q. The IFU and the other material and  
11 conversations you had, did you find that was helpful to  
12 you in treating the complications?

13 A. Discussing with colleagues and review of  
14 manuscripts was. I'd have to say that the IFU for the  
15 procedure was helpful, how it was going, the management  
16 of the complications, no.

17 Q. How prevalent has been your treatment of  
18 mesh complications, including Prolift® complications,  
19 in your practice?

20 A. Well, it depends what time frame you're  
21 talking about. 2005, uncommon; as the time goes on,  
22 more and more common, such that in any given week I'm  
23 seeing three to five or maybe more patients with  
24 various different mesh complications, including the



1 Prolift®.

2 Q. Have you actually spoken at any national  
3 meetings to other physicians about the treatment of  
4 mesh complications?

5 A. Well, numerous times, most -- numerous  
6 times and most recently in February, again, at that  
7 SUFU meeting, Society of Urodynamics & Female Urology,  
8 where I was the invited lecturer on management of  
9 complications of the mesh.

10 Q. Have you previously been qualified as an  
11 expert in a Federal Court case with regard to the  
12 Prolift®?

13 A. Yes.

14 MR. ISMAIL: Objection, 403.

15 MR. SLATER: We offer Dr. Elliott as an  
16 expert in the fields of urology and female  
17 pelvic medicine and reconstructive surgery.

18 MR. ISMAIL: We'll reserve for our  
19 qualifications for cross.

20 BY MR. SLATER:

21 Q. Doctor, in the course of your testimony,  
22 I'll be asking you to -- if you have opinions on  
23 certain issues.

24 You realize that, right?

1 A. Yes.

2 Q. In the course of your testimony, do you  
3 understand that if you offer an opinion, whether I ask  
4 you for an opinion or if you offer it in the course of  
5 your testimony, that it must be to a reasonable degree  
6 of medical certainty?

7 A. Correct.

8 Q. So that I don't have to keep repeating  
9 that phrase over and over, can we have an understanding  
10 that if you offer an opinion, it will be to a  
11 reasonable degree of medical certainty, or you will  
12 tell us otherwise?

13 A. Yes.

14 Q. Okay. What I'd like to do now is you have  
15 a list of materials reviewed, correct?

16 A. Yes, I do.

17 Q. And just tell us what that list is.

18 A. It's a fairly brief summary of all the  
19 materials that I've reviewed pertaining to the mesh and  
20 specifically Prolift®. Number one was the medical  
21 literature that I reviewed, that would have been mainly  
22 through PubMed, which is the largest search engine for  
23 medical literature, clinical and preclinical studies.  
24 Ethicon and J&J internal documents and videos, surgical

1 videos usually. Ethicon and J&J current and former  
2 employees' depositions, which there's a large number of  
3 those, which we did not glean out each one, but there's  
4 a large number. Depositions of the Ethicon consultants  
5 and the New England Journal of Medicine editors and,  
6 lastly, Ethicon and J&J product labeling and marketing  
7 documents, like the IFU and patient brochures.

8 Q. Those categories of information, you've  
9 set forth a reliance list of what you've relied on in  
10 this case?

11 A. Yes.

12 Q. Okay. With regard to the Johnson &  
13 Johnson and Ethicon internal documents that were not  
14 publicly available, was that significant information to  
15 you in forming your opinions in this case?

16 A. Very much so, yes.

17 Q. Why is that?

18 A. Because as a surgeon active in practice,  
19 attending meetings, reviewing of the medical  
20 literature, that gives me one side of complications or  
21 what is known. What I was unaware of prior to this  
22 litigation is what was the degree, severity of the  
23 complications that were known prior to that and was not  
24 available to the -- say, the average doctor on the

1 street.

2 Q. Let's go to an exhibit that's on the top  
3 of your pile there P1306, which is Prolift® patient  
4 brochure.

5 Is this a document you're familiar with?

6 A. Yes, it is.

7 Q. Is this a document you've relied on in  
8 part in forming your opinions in this matter?

9 A. That is correct.

10 Q. What I'd like to do is just for  
11 illustrative purposes turn to Page 5, please, and there  
12 is a diagram of normal pelvic anatomy.

13 And the jury will have this up on their screen  
14 to see. Can you just tell the jury very simply what of  
15 significance is shown in this simple illustration?

16 A. Well, it's a cartoon or a schematic of the  
17 female pelvis in a coronal or going down the middle,  
18 and it's just showing the anatomy with the bladder,  
19 urethra, vagina and uterus. It's a quite simplified  
20 anatomy view for a patient.

21 Q. Now, let's turn to the next page, Page 6,  
22 and there's an illustration of a cystocele, and can you  
23 tell the jury what they're seeing there?

24 A. Yes, this in comparison to the first

1 picture, which was normal anatomy, the second one now  
2 has a schematic -- again, understand it's in a very  
3 simplified form, which there's nothing wrong with that,  
4 but it's just showing the anterior bladder wall falling  
5 down, which is called a cystocele.

6 Q. Why does that happen? What is it  
7 physiologically that happens that allows the bladder to  
8 bulge down into the vagina?

9 A. Be multiple different factors, increasing  
10 age, childbirth, possibly hysterectomy, obesity,  
11 chronic cough, factors like that that increase the  
12 strain on the pelvis that would have the tissue weaken  
13 over time and then fall down.

14 Q. When you refer to the tissue, you're  
15 talking about the tissue of the pelvic floor?

16 A. That's correct, the vaginal tissue,  
17 though, technically, it's the tissue underneath the  
18 vagina that's holding things up and it's weakened  
19 because of those aforementioned factors.

20 Q. Let's turn to the next page. Let's turn  
21 to Page 7 of the patient brochure. There's an  
22 illustration of a rectocele. Can you just tell us  
23 simply what that is showing.

24 A. Yeah, a rectocele, think of it as just the

1 opposite of what I described of where the bladder is  
2 falling down, as we say, into the vagina, this is where  
3 the rectum is ballooning up into the vagina, again,  
4 because of those other issues of pregnancy, childbirth  
5 and weakening of the tissues.

6 Q. There's a diagram on Page 7 of uterine  
7 prolapse. Very simply, what is that?

8 A. Again, similar to the other issues, this  
9 is where the uterus is falling down, again, due to lack  
10 of support or weakened support.

11 Q. Is surgery required for all pelvic organ  
12 prolapse?

13 A. No.

14 Q. Is it an elective surgery or a surgery  
15 that must be done in the vast majority of cases?

16 A. It is a quality -- it's very important to  
17 emphasize this, it's a quality of life problem, meaning  
18 the patient is really in charge as far as the  
19 decision-making. So for the majority of individuals in  
20 my practice, observation or conservative therapies are  
21 done. It is very rarely in the United States a  
22 necessity that surgery has to be done.

23 Q. Let's turn to the list of treatment  
24 options. It would be the second PowerPoint slide,

1 treatment options for pelvic organ prolapse, and I'll  
2 ask you to briefly go through the list and tell us what  
3 each of them -- what each of these options are?

4 A. It's a summary that made up of options or  
5 historical options for treatment of pelvic organ  
6 prolapse in women. As I mentioned, it's a quality of  
7 life problem. So the first option is observation and  
8 being conservative, just reassuring the patient that if  
9 it's not bothering them, don't do anything. If it's  
10 minimally bothersome, you know, you may or may not  
11 choose to do something.

12 Next option is a pessary, which is a -- kind of  
13 think of it like a plug, a silicone or a plastic plug  
14 being placed in the vagina to help hold things up.  
15 Historically, that was done a lot, now a little bit  
16 less so, but still it's a conservative, nonsurgical  
17 option.

18 Q. Basically, it would be placed under the  
19 bladder to hold the bladder up?

20 A. It's placed in the vagina underneath the  
21 bladder to either hold up the bladder, hold up the  
22 uterus or hold up the rectum, dependent upon what  
23 problem they're trying to fix.

24 The next one is the traditional sutured

1 repairs, like the colporrhaphy. Colporrhaphy just  
2 means repair of the vagina, so you can have an anterior  
3 colporrhaphy of the bladder, posterior colporrhaphy for  
4 rectum, and that's using sutures, the traditional type  
5 of repair, which I do very commonly.

6 We also mentioned briefly here the sacrospinous  
7 ligament fixation and uterosacral ligament fixation.  
8 Those are for what's called vault prolapses, where the  
9 whole vagina is falling out, so through the vagina, you  
10 can suture it to various different structures to  
11 provide support.

12 And then you have the transabdominal  
13 sacrocolpopexy. This is a procedure that can be done  
14 either with an incision or done laparoscopically or  
15 done with a robot, which is my preferred route.

16 Q. What does that mean laparoscopically or  
17 with a robot?

18 A. The procedure is fixing the vagina up to  
19 the sacrum. It can be done with an incision, where  
20 it's opened up, or using a laparoscope, which is  
21 cameras through little ports, four or five ports or  
22 using a robot, which is basically a robot attached to  
23 the cameras looking in. It's a different way of doing  
24 it.



1           The next is biologic grafts. This is where you  
2    can use either tissue from a tissue bank, like  
3    cadaveric tissue, which is not the patient's, but it's  
4    human, or you can use xenografts, which is coming from  
5    a different source, like pig or cow. And then you also  
6    have synthetic grafts, which is a mesh that's placed in  
7    the vagina.

8           Last on the list is the mesh kit, in this  
9    particular case the Prolift®, but it can be multiple  
10   other mesh kits out there.

11           Q.   What are the most prevalent surgical  
12   procedures for the treatment of prolapse?

13           A.   Currently as far -- well, again, it  
14   depends upon what type of prolapse you're talking  
15   about, because there's going to be a lot of different  
16   ones.

17           Q.   Let's talk about, for example, a  
18   cystocele.

19           A.   Cystocele would be an anterior  
20   colporrhaphy. The traditional nonsutured repair would  
21   be most common.

22           Q.   Are the various abdominal sacrocolpopexies  
23   that you described both open and laparoscopic or  
24   robotic prevalent as well?

1           A.     They're very common, but, again, that's  
2     for total vaginal vault prolapse, yes, and depending on  
3     the various different regions, like in the south, it is  
4     the most common procedure performed for that common  
5     problem.

6           Q.     Doctor, I'm going to now hand across the  
7     table to you what we are marking as P2810, and this  
8     would be the actual Prolift® anterior repair kit, and  
9     what I'll ask you to do first is just to show the jury  
10    what the Prolift® kit is. We've obviously started to  
11    open it to save time, and the camera will show the  
12    instruments and tell the jury what we're seeing there.

13          A.     Well, important probably, let's go back to  
14    the basics. It comes as a kit. So what the surgeon  
15    gets is a kit in a box.

16          Q.     And I'll hand you the box, which also has  
17    the booklet in it as well.

18          A.     Which the nurse brings this to you, takes  
19    it out of the box. The surgeon opens it up, and so  
20    it's a contained kit, as opposed to multiple different  
21    pieces. It's a self-contained operation, a kit.

22                 So then you're going to have the various  
23    different components of the kit, which you will have  
24    the trocar, however long that is, 15 inches or so

1 curved. It's curved for gaining access, we can go into  
2 it later, as far as through the obturator foramen or  
3 how this goes in, so it goes in through it and --

4 Q. What does that mean? If you're going to  
5 say something technical, you might as well tell the  
6 jury, obturator foramen.

7 A. You have the pelvis, male or female,  
8 doesn't matter, you have the obturator foramen, which  
9 are the holes off to the side, kind of look like this.  
10 As I explain it to residents, I go like this is how it  
11 is. So you have the vagina here and then these  
12 obturator foramen which are the big bones attached to  
13 it with overlying muscles, gracilis, abductor longus, a  
14 bunch of -- four or five different muscles overlying  
15 this.

16 So when you're gaining access to the vagina,  
17 you will go through the obturator foramen from the  
18 outside in and go down to the vagina. So there will be  
19 a surgeon's hand in the vagina to grab this. Again,  
20 this is the trocar gaining access going through those  
21 muscles, through the obturator foramen into the vagina.  
22 You should have this loaded up here, then there's the  
23 cannula that actually goes over this.

24 So when the surgeon goes in, then he pulls it

1 on out, so we don't have to go into detail now, but a  
2 cannula is another part of it. And then the -- you'll  
3 have a retrieval system here, and then, lastly, you'll  
4 also have the mesh. Now, again this is an anterior  
5 mesh.

6 Q. What is that used to treat?

7 A. This is to treat anterior prolapse, okay,  
8 the bladder, a cystocele, okay.

9 Q. So if the bladder is dropping down on to  
10 the vagina or into the vagina, this is for the  
11 treatment of that condition?

12 A. Correct. There will be three different  
13 types of meshes predesigned, precut meshes, one for  
14 anterior like this one here. This will show up very  
15 well, may show up a little better like this that can be  
16 seen with arms on it, four arms going out those  
17 obturator foramen, which I had mentioned. The  
18 posterior will have a different configuration, and then  
19 the total will be a combination of the anterior and  
20 posterior.

21 Q. When you showed the guide and the cannula,  
22 is that ultimately to set the tunnels to pull the arms  
23 back out of the body?

24 A. Correct, correct, yeah.

1           So this will go from the outside through the  
2   obturator foramen into the vagina. This is pulled out.  
3   The retrieval device is placed through it and then the  
4   mesh is pulled through it. So at the at the end of the  
5   procedure, this is very important, all of these, the  
6   trocar, the retrieval device and the cannula are no  
7   longer with the patient. The only thing that's  
8   remaining is the mesh.

9           Q.   Now, we have here -- we've marked this as  
10   Exhibit 2292, a total repair kit, and what I'll ask you  
11   to do, keep it separate, I really just want you to be  
12   able to -- to pull out the mesh part.

13                   MR. ISMAIL: Objection to the relevance.

14   BY MR. SLATER:

15           Q.   If you could, please show the jury the  
16   total Prolift® implant.

17           A.   I'll just keep it in the plastic here,  
18   actually show it a little better here.

19                   So you have the total Prolift®, where you have  
20   the anterior component of it or part right here, that's  
21   what I showed just a second ago (indicating).

22           Q.   That's for treatment of a bladder  
23   prolapse?

24           A.   Bladder or anterior prolapse, a cystocele.

1 Then you have the posterior aspect up here with the  
2 various different arms, again, the arms are configured  
3 differently because they're exiting out the -- they're  
4 not going through the obturator foramen, they're  
5 actually going through the buttocks. So you can get an  
6 idea of the volume of the meshes and the arms and the  
7 shape. This is treating a total vaginal vault  
8 prolapse.

9 Q. And the posterior part of the Prolift®,  
10 that's to treat a rectocele or rectal prolapse?

11 A. The posterior is for rectocele, that is  
12 correct, yes. The total would be for anterior  
13 cystocele, enterocele like the intestines are pushing  
14 down and rectocele, so it's treating the whole vault.

15 Q. I'll take that.

16 Doctor, in your career have you ever used the  
17 Prolift®?

18 A. No, I have not, by choice.

19 Q. Do the other doctors at the Mayo Clinic  
20 use the Prolift®?

21 MR. ISMAIL: Objection, lack of  
22 foundation.

23 MR. SLATER: Rephrase.

24 BY MR. SLATER:

1 Q. Did the other doctors at the Mayo Clinic  
2 use the Prolift®?

3 MR. ISMAIL: Objection, lack of  
4 foundation, hearsay, 403.

5 THE WITNESS: No, all by choice  
6 separately, just chose back in 2005 in that  
7 time frame not to use it.

8 BY MR. SLATER:

9 Q. Why did you chose not to use the Prolift®?

10 A. I didn't see a need for it.

11 Q. What do you mean by that?

12 A. In my practice we had good success, good  
13 quality of life, low recurrence rate, and I didn't see  
14 a purpose for it.

15 Q. When the Prolift® first came out, did you  
16 look to see if there was data to support the use of the  
17 Prolift®?

18 A. Right when it first came out, no. We're  
19 going back a lot of years now. I remember looking and  
20 reviewing it because there was a lot of interest in  
21 female urology. This is my first year -- five years in  
22 practice, and it was new, it was different, and so I  
23 looked into it. I don't recall the literature I  
24 reviewed at that point in time, but, again, I just

1 decided I didn't see a need.

2 Q. Okay. I'd like you to look now at Exhibit  
3 1593 and this is a Prolift® professional education  
4 PowerPoint slide deck.

5 Are you familiar with this document?

6 A. Yes, I am.

7 Q. Is this something you've relied on in  
8 forming your opinions?

9 A. Yes, it is.

10 Q. What I'd like to do is turn you towards  
11 the back, actually, about seven or eight pages from the  
12 back, there's an illustration of the anterior implant  
13 position.

14 Do you have that?

15 A. This one?

16 Q. Yes. Great.

17 A. Doesn't look like we have a page number on  
18 it.

19 Q. There's no page numbers on it but --

20 A. That one.

21 Q. Great. It will certainly be up on the  
22 screen for the jury.

23 Can you tell the jury what this is showing,  
24 this simple schematic?



1           A.    This is, assuming we're on the same  
2   page -- we are on the same page, correct?

3           Q.    Yes.

4           A.    Okay. This is a schematic, again, a  
5   cartoon or a simplified version of the actual anterior  
6   mesh in-situ, meaning in the patient and where it goes,  
7   where the arms go and things.

8           Q.    What are the structures that we see, just  
9   to orient us?

10          A.    Well, it's quite simplified because a lot  
11   of the important things are not there. But you can see  
12   the bladder, you can see underneath it the mesh and  
13   then under that you can see the vagina. And then you  
14   see the rectum and you see the obturator foramen and  
15   various different ligaments around the pelvis, but,  
16   again, it's quite simplified.

17          Q.    The bladder would be to the front, the  
18   rectum would be to the back as the jury sees this?

19          A.    As you go down you have bladder, mesh,  
20   vagina, rectum from top to bottom.

21          Q.    If you turn -- this is actually the 55th  
22   page of the slide deck, just for the record. If you  
23   turn back one page to the -- actually turn forward one  
24   page, okay, on the 54th page of the slide deck, I

1 believe it is -- it says Gynecare Prolift® Total  
2 Implant Position.

3 What is that showing us?

4 MR. ISMAIL: Objection, relevance, 403.

5 THE WITNESS: Okay. That's showing --  
6 it's a continuation of the volume of mesh  
7 that's put in. It shows the anterior and  
8 posterior mesh in place as it would  
9 theoretically be supporting the bladder, the  
10 apex of the vagina and then the posterior  
11 aspect which is where the rectum would be.

12 BY MR. SLATER:

13 Q. Okay. Now, what I'd like to do, if we  
14 could, is go through some animation video clips. Are  
15 these video clips that you have selected and that you  
16 have reviewed as part of your review of this case?

17 A. That is correct, yes.

18 Q. Are these animation videos something  
19 you've relied on in forming your opinions?

20 A. Yes.

21 Q. Do you, in your opinion, feel they would  
22 be useful to you in demonstrating aspects of the  
23 procedure and illustrating your opinions in this case?

24 A. Very much so, yes.

1           Q.    Okay.  We are going to play the video  
2   clips with no sound, and they are short video clips,  
3   and the first one is a short one.  It's 501 for the  
4   record.

5           MR. ISMAIL:  Just we object under 403 to  
6   the playing or showing to the jury of any of  
7   the video of the actual surgery itself.

8           MR. SLATER:  Okay.  We're starting with  
9   the animation clips.

10          MR. ISMAIL:  Fair enough.

11          MR. SLATER:  Is there an objection to the  
12   animations?

13          MR. ISMAIL:  Depends what you show.

14          MR. SLATER:  There's not a blanket  
15   objection, initially?

16          MR. ISMAIL:  Not a blanket objection.

17   BY MR. SLATER:

18          Q.    Okay.  Doctor, what we're going to do,  
19   before we show this, clip 501 we're going to put it up  
20   on the screen, and then you'll just tell the jury,  
21   we'll pause it about halfway through when it gets set  
22   up, and then you can tell the jury what they see, okay.

23                (Video played.)

24   BY MR. SLATER:

1 Q. What is that showing us?

2 A. Okay. Again, it's just showing the  
3 anterior Prolift® mesh, as it would be placed in the  
4 patient as far as somewhat of its orientation, and then  
5 the female pelvis in what's called the dorsal lithotomy  
6 position, just the way you operate, a woman on her  
7 back, legs up in stirrup and then access to the vagina.  
8 And then you can see underneath it is the pelvic bones,  
9 how they would be in the woman when she's on her back.

10 Q. Just for the record, you're turned a  
11 little to the side because you're looking at a screen  
12 on the wall?

13 A. Yes, I am. There's a screen over here.

14 Q. Okay. We're going to now go to clip 502.  
15 What are we going to see here?

16 A. On 502?

17 Q. Yeah, let's play -- actually, let's play  
18 it and then if you want to have him pause it or you  
19 certainly can tell him to pause it at a certain time  
20 and explain what we're seeing.

21 A. Yeah, it's just describing -- you can  
22 pause it a second there very quickly. It initially  
23 highlighted the arms, which is a very key component to  
24 the Prolift® mesh, which makes it unique compared to

1 the other operations I discussed, where the arms would  
2 be going through the obturator foramen. That's why it  
3 highlighted the more out -- proximal vagina and then  
4 deep vagina. So those arms go in different locations.

5 Q. What I actually want to do now is I want  
6 to go back to the start on this clip.

7 A. Okay.

8 Q. Let's go back. We're not going to be able  
9 to pause it because it's going to be played in other  
10 courts potentially, and they're not going to be able to  
11 know when you paused it. So what I'm going to do is  
12 I'm just going to have the clip played.

13 A. Okay.

14 Q. And this is -- I'm just saying this for  
15 everyone in the room, probably realize that was kind of  
16 silly what I just did, hope everybody had a good giggle  
17 out of it. We're just going to show it from the  
18 beginning when I'm ready to start, and then you'll just  
19 narrate as it goes, and then when it's done, you can  
20 explain if there's anything else you have to explain.

21 So let me start over. That was just for  
22 everyone in the room to know -- get their jollies here.

23 Doctor, we're now going to show animation clip  
24 502. As it plays, would you please explain to the jury

1 what they're seeing.

2 A. Sure. It's a schematic again showing the  
3 mesh with highlighting the various different arms that  
4 go through the obturator foramen, which I've discussed  
5 just a little earlier and then place it in the vagina  
6 how it will be done, with an incision. They described  
7 there a fairly small incision. Now you've turned  
8 sideways, and then they'll place the mesh through that.

9 Q. And the mesh is placed through the vagina  
10 through a vaginal incision?

11 A. Correct.

12 Q. Next we're going to go to clip 504A, and  
13 what we'll do is, again, we'll show it and please tell  
14 the jury what of significance they're seeing, please.

15 A. Okay. Now, this is a surgeon with a  
16 finger placed through the vagina through the vagina  
17 incision, now, those trocars, which I showed just a  
18 little while ago, going through the obturator foramen  
19 through multiple different muscles, there they show one  
20 of the muscles. There's other ones. Again, there's  
21 four or five different large muscle groups that it goes  
22 through, through the vagina, on to the surgeon's index  
23 finger, and then they will first place the distal most,  
24 see there, toward the opening of the vagina. There's

1 where the first one goes through, ideally through the  
2 arcus tendineus, which is an anatomical strong  
3 structure.

4 Q. Okay. Now, let's go to animation clip  
5 505, please, and just again narrate through for the  
6 jury what is significant to you.

7 A. Again, we have the schematic and now the  
8 arms are already placed through. We've actually missed  
9 a step. There's another video in there describing how  
10 they placed the other ones, but this is how the mesh  
11 wraps through the retrieval device and then will be  
12 pulled out through the skin, through the vagina,  
13 through the skin and out.

14 Q. And I think -- well, rephrase.

15 Let's go to clip 506 now, and can you tell the  
16 jury what they're seeing there.

17 A. Okay. Again, this is the placement  
18 through the retrieval devices of all the four arms that  
19 will go through the vagina and out the obturator  
20 foramen through those cannula that I described earlier,  
21 and now the cannulas are being removed and the mesh is  
22 then being slid into place. The cannulas then are  
23 removed. Here's where it shows the mesh lying flat in  
24 there, again, in the cartoon fashion.

1           Q.    Doctor, we're not going to go through the  
2   total or posterior Prolift® procedures in the interest  
3   of time.

4           The video animation clips that we just showed  
5   for the anterior procedure, are they a fair  
6   demonstration of those steps of the procedure in a  
7   general sense of what is done to get the mesh into the  
8   body and the arms out?

9           A.    Well, it's very -- it's a schematic. I  
10   don't know -- I would argue on the word fair, but it's  
11   showing how it goes through because it's very  
12   simplified form of it, yes, let's put it that way.

13          Q.    What I meant is does it, in a general  
14   sense, demonstrate what would happen in the posterior  
15   or total procedures as well?

16          A.    Yes, in a very general sense, but I'd say  
17   it would be misleading, though.

18               MR. ISMAIL:  Objection, move to strike,  
19               nonresponsive.

20   BY MR. SLATER:

21          Q.    Doctor, the clip that we just -- the clips  
22   that we just saw of the anterior procedure, do they  
23   generally show how the mesh in an animated, simple form  
24   is placed into the body and the arms are pulled out?



1 A. Yes.

2 Q. Doctor, what is the mesh material in the  
3 Prolift®, what is it called?

4 A. It's -- well, the basic is polypropylene  
5 mesh.

6 Q. And what is it called, what's the name of  
7 the mesh?

8 A. Gynemesh®.

9 Q. And was that originally developed to be  
10 used in the pelvis or for another use?

11 A. Another use.

12 Q. What's that?

13 A. For hernia repair, abdominal hernia  
14 repair.

15 Q. And that was called Prolene Soft when it  
16 was developed for hernia?

17 A. That is correct.

18 Q. When Gynemesh® mesh started -- Prolene  
19 Soft mesh started to be marketed for use in the pelvis,  
20 it was first marketed in about 2003; is that correct?

21 A. Roughly in that time frame, yes.

22 Q. And when it was first sold as Gynemesh®  
23 PS, was it sold in a kit like this or was it sold  
24 differently?

1           A.    No, it was not in a kit, it was just a  
2   sheet of polypropylene.

3           Q.    And what did doctors do with that mesh  
4   when it was first sold as Gynemesh® PS?

5           A.    The surgeon would trim it, tailor it to  
6   the given patient and place it through the vagina.

7           Q.    And just would use a portion of the mesh  
8   to help support a suture repair as-needed?

9           A.    That is correct. It would be to tailor,  
10   to repair whatever they're repairing.

11          Q.    We're going to talk more about this a  
12   little later, but do you have an opinion as to whether  
13   the use of Gynemesh®, just cutting a portion of it and  
14   placing it in the vagina for a particular patient's  
15   needs, whether or not that is a safer alternative than  
16   the Prolift® with the larger amount of mesh and the  
17   arms that we've seen?

18               MR. ISMAIL: Objection, lack of  
19               foundation. I don't believe this is a  
20               disclosed opinion.

21   BY MR. SLATER:

22           Q.    You can answer.

23           A.    I would be very careful what I say -- I  
24   would say it would be a safer procedure. I do not

1     agree with it being safe, but it is safer than the kit  
2     with arms, et cetera.

3             Q.     And we'll talk more about it later, but  
4     very succinctly, what's the reason why?

5             MR. ISMAIL:   Objection, lack of  
6     foundation, undisclosed opinion.

7             THE WITNESS:   There would be multiple  
8     factors.   The largest one would be the sheer  
9     volume of mesh, but then also the trocars with  
10    the arms going through the various different  
11    muscle groups, because that is going to fix  
12    this mesh in a completely different way.

13    BY MR. SLATER:

14             Q.     Doctor, next exhibit is PLT0062, not a  
15    PowerPoint, but it's an actual document.

16             MR. ISMAIL:   Copy.   While you're at it,  
17     can I have the other one.   I didn't want to  
18     interrupt while you did the video.   Thank you.  
19     These are the 504s and the 506s?

20             MR. SLATER:   They are, and we can -- we'll  
21     get you the actual clips if you don't have  
22     them.   They're exactly the same as what was  
23     utilized in Bellew, so you guys should have  
24     them, but we can have them Dropboxed or sent

1 over to you.

2 MR. ISMAIL: Thank you.

3 BY MR. SLATER:

4 Q. Okay. Doctor, I've handed you PLT0062.

5 Is this a medical journal article you are  
6 familiar with?

7 A. Yes, it is.

8 Q. Is this an article that you feel and  
9 believe to be medically reliable in the field?

10 A. Yes, it is, yes.

11 Q. Is this something you've relied on in  
12 forming your opinions?

13 A. Yes.

14 Q. First of all, who wrote this article?

15 A. Well, it's a TVM group, as they call them.  
16 There's multiple different authors involved, six, I  
17 believe.

18 Q. What was the role of the TVM group, this  
19 group of doctors from France, what was their -- very  
20 simply their role with the Prolift®?

21 A. Well, a group of physicians got together,  
22 these surgeons that are mentioned here, in France, as  
23 you stated, to devise this new technique for prolapse  
24 repair using the polypropylene mesh.

1           Q.    If you could, turn to the fourth page is  
2   Page 579, and what I want to focus on in the bottom  
3   right corner, there's a -- I guess a blowup of a  
4   microscopic picture of the -- or a close-up picture of  
5   the soft Prolene mesh. That's the mesh in the  
6   Prolift®?

7           A.    That is correct.

8           MR. ISMAIL:  Objection, hearsay.

9           THE WITNESS:  Yes, that's correct.

10   BY MR. SLATER:

11           Q.    And just focusing on that one box that  
12   says soft Prolene on it, what are we seeing there?  
13   What's of significance?

14           MR. ISMAIL:  Objection, hearsay. I don't  
15   want to keep interrupting. I have a standing  
16   objection to hearsay to the use of this  
17   article. Okay. I'll keep objecting.  
18   Objection, hearsay. Sorry, I didn't mean to  
19   interrupt.

20           MR. SLATER:  Let me just ask, I don't  
21   understand your hearsay objection. It's a  
22   medical literature.

23           MR. ISMAIL:  Objection, hearsay.

24           MR. SLATER:  You think they're not useful,

1           you can't use medical literature in a trial?

2           MR. ISMAIL: This article is hearsay.

3           MR. SLATER: You don't have to object to  
4           the use of my articles on the hearsay basis  
5           anymore during this deposition. That's  
6           preserved.

7           MR. ISMAIL: I'm probably going to, given  
8           that I think we have a disagreement as to  
9           whether learned treatises are hearsay or not.

10          MR. SLATER: All right. But I'm saying  
11          I'm granting you a standing objection to my use  
12          of learned treatises as hearsay that is  
13          inadmissible, so you don't have to object it  
14          because you can -- every time I use medical  
15          literature, you can object to it and say it was  
16          hearsay and shouldn't be allowed to be used, so  
17          that way we can move through, is that okay? It  
18          will help me to not have you objecting when I'm  
19          already agreeing you have a preserved  
20          objection.

21          MR. ISMAIL: I appreciate that. What I'll  
22          do is every time you introduce a new article,  
23          I'll object to that one as being hearsay, and  
24          if I have a standing objection to the use of

1           that particular article, I won't keep  
2           interrupting.

3           MR. SLATER: You have a standing objection  
4           to my use of medical journal articles.

5           MR. ISMAIL: I have an objection to this  
6           article, Exhibit 62, Plaintiffs' Exhibit 62, as  
7           hearsay, and I appreciate the standing  
8           objection to the use of this article.

9           MR. SLATER: Sure, and it's for the record  
10          PLT0062.

11          MR. ISMAIL: Yes. Thank you.

12 BY MR. SLATER:

13          Q. Okay. Doctor, I'm going to start over.

14          On Page 579 of this article, there is an  
15          illustration and a close-up picture of soft Prolene  
16          mesh.

17          Do you see that?

18          A. That is correct, yes.

19          Q. Is that the mesh material in the Prolift®?

20          A. Yes, it is.

21          Q. What is of significance that we're seeing  
22          here?

23          A. Well, they're just showing -- you have to  
24          take it in all -- there's four different photographs.

1           Q.    We're only looking at the soft Prolene  
2   picture.

3           A.    They're just showing the mesh, the weave  
4   of the mesh, the space of the meshes.

5           Q.    What do they call -- what are those spaces  
6   referred to as?

7           A.    The pore size would be the easiest one,  
8   the gate in between them, the space in between the  
9   various meshes.

10          Q.    We have -- you see there's some larger  
11   spaces and they have a thread right through the middle.

12          Do you see those?

13          A.    Yes, I do.

14          Q.    There's also knots and spaces there. What  
15   are those referred to as?

16          A.    Well, again, there's a -- all the meshes  
17   have a different weave to them. So this is the weave  
18   of the mesh and the areas where it's all knotted, as  
19   you mentioned.

20          Q.    So it's showing the actual appearance of  
21   the pores and the interstices between the mesh?

22          A.    Correct, on a relatively microscopic or  
23   magnified view.

24          Q.    When the mesh is in the body after the



1 surgery, and now that this incision is closed, what is  
2 supposed to happen? What was intended to happen with  
3 the healing process and with the mesh in the body?

4 A. Well, theoretically, as you see here, the  
5 picture has large pores, now, again, this is magnified,  
6 so we have to take that, but, theoretically, you are  
7 going to have the tissues grow through those to get  
8 nice healthy tissue in between those pores, that's in  
9 theory. It would be like a scar net is the kind of  
10 phrase that was used. But, again, that's in theory  
11 what would happen.

12 Q. What actually occurs in practice based on  
13 your review of the materials, the medical literature,  
14 your medical experience, all the materials you  
15 reviewed, what is it that actually occurs?

16 MR. ISMAIL: Objection, lack of  
17 foundation, 705.

18 THE WITNESS: Okay. In my daily practice  
19 on physical exams in people with Prolift®, what  
20 actually happens when that Prolift® gets in  
21 there, or any mesh, for that matter, not just  
22 Prolift®, but let's just talk specific to  
23 Prolift®, the mesh is going to be pulled, the  
24 pore size is going to decrease, and then

1           instead of getting this intergrowth through the  
2           holes of the mesh and have nice healthy tissue,  
3           you then get a scar plate. So the scar forms  
4           around this.

5                       So where it's important for me is then on  
6           physical exam, when you do a pelvic exam, you  
7           feel this fibrotic or wooden, what you kind of  
8           describe it as, again, this firmness within the  
9           vagina.

10    BY MR. SLATER:

11                   Q.    What is it that leads to the development  
12    of scar tissue, what is it about the interaction of the  
13    mesh in the body that leads to that?

14                   A.    Well, that's a long, drawn out  
15    conversation because what you've got, you've got a  
16    foreign body --

17                   Q.    Let's do it not the long, drawn out  
18    conversation version.

19                   A.    All right, we'll be specific. Mesh is not  
20    human, it's foreign. You put it in the body, the body  
21    perceives it as foreign. The body's natural response  
22    is to try to get rid of it, and the process starts to  
23    create this foreign body reaction, which increases the  
24    scar tissue, that causes the mesh to contract or the

1 tissue to contract around it, which then perpetuates  
2 the problem. That's why it's a progressive problem.  
3 So it's a long, drawn out conversation. That's a very  
4 succinct answer.

5 Q. As part of the foreign body reaction, is  
6 there any inflammatory response as well?

7 A. Well, that is part of it, okay. The body  
8 perceives the mesh as foreign, which it is. The  
9 response of the body is to create inflammatory  
10 response. So as long as that foreign body is in there,  
11 you're going to have an inflammatory process.

12 Q. With regard to the size of the pores in  
13 the Prolift® mesh or any mesh, is there an  
14 understanding as to whether or not larger spaces or  
15 smaller spaces are better in terms of the healing  
16 process?

17 A. The larger the space, the space in between  
18 the mesh, the reduced inflammatory and foreign body  
19 reaction you're going to have.

20 Q. There's been reference, and tell me if  
21 you're familiar with it, to a 1 millimeter pore size in  
22 all directions under strain.

23 Is that a concept that's of any significance to  
24 you?

1 A. Yeah, it's a very important concept.

2 Q. Why is that?

3 A. Saying that -- again, you made a very good  
4 point there as far as when it's in the body, under  
5 strain. It doesn't matter what it's doing on the  
6 table. As I hold up this mesh, that doesn't matter.  
7 What matters is is when it's in the body and when it's  
8 being pulled on when the woman is walking, coughing,  
9 doing activities, what those pores do. Those pores  
10 contract down, then you're going to start this whole  
11 cascade, the scar plate, the inflammatory response,  
12 foreign body reaction.

13 Q. What happens to the pores when the  
14 Prolift®, as we've seen in those schematics, gets put  
15 into the body, what happens to the pores?

16 A. Collapses.

17 Q. What do you mean by that?

18 A. Means, again, we have this picture of  
19 these large pores, okay, when you start to pull on it,  
20 when you place it, just the arms, you're going to have  
21 to pull on those arms, you're going to have to tension  
22 this, and then those pores go from this to collapsed  
23 down like this (indicating). When that happens, now  
24 the body can't grow through it, like that scar net I

1 described. Now you get that caking, and we can feel it  
2 when we do physical exams on Prolift®, the banding we  
3 call it, feel out lateral in the vagina, and you feel  
4 this rod, for lack of a better phrase, you touch it, it  
5 hurts. It's a whole cascade of everything I've  
6 mentioned several times now.

7 Q. What is contraction or shrinkage, what  
8 does that mean?

9 A. That's when, again, we go back to this  
10 foreign body reaction, inflammatory response, the body  
11 is trying to healing itself. The only way it can is by  
12 creating scar. When that happens, the scar contracts  
13 down, pulling the mesh. The mesh is the ultimate  
14 responsibility, but it pulls on it, okay, and the  
15 significance of mesh contraction is pain, because, like  
16 I mentioned in that video, where these trocars are  
17 going through all those muscles and mesh is going  
18 through those muscles, muscles hurt when you start to  
19 pull on them. So as the mesh contracts, pulls  
20 together, pulls on those muscles of the pelvis and it  
21 causes the pain.

22 Q. Doctor, if you could go back to the  
23 professional education PowerPoint, 1593, it's the  
24 larger one right there, top left, and it's about the

1 tenth page in, and actually I counted them, I think  
2 it's the tenth page, and there is a slide that says  
3 "Mesh Use in Hernia Surgery" and has a picture of  
4 rebar.

5 A. Yes.

6 Q. Is this of significance to you, this  
7 illustration and the language next to it?

8 A. Yes.

9 Q. Tell the jury, first of all, it says,  
10 "Much like rebar in concrete, the stress at any one  
11 point is distributed over the entire area of the  
12 graft."

13 Do you see that?

14 A. Yes, I do.

15 Q. Now, have you seen anything in any medical  
16 literature or any material you've ever seen that shows  
17 that when the Prolift® is placed, it actually has this  
18 distribution of stress across the entire mesh, like  
19 they say in the engineering rebar?

20 A. Well, no, it's the exact opposite,  
21 actually.

22 Q. And so using this diagram, what's the  
23 significance of this picture of rebar?

24 MR. ISMAIL: Objection, lack of

1 foundation, 705.

2 THE WITNESS: Well, the rebar analogy is  
3 accurate and completely inaccurate at the same  
4 time. Yes, I agree, it's a very strong  
5 substance, unbending, but when it's placed in  
6 the human body, that's not what you want. You  
7 need to have something dynamic that can move,  
8 and so that's why I say it's correct and it's  
9 incorrect. It's very, very strong, but that's  
10 not what you want having placed in the vagina.

11 BY MR. SLATER:

12 Q. If rebar has to be removed from the  
13 sidewalk, you take the jackhammers and chop down into  
14 the concrete and get it out?

15 MR. ISMAIL: Objection, 403.

16 THE WITNESS: Which I have done in between  
17 high school and college, and it is a bear.  
18 That's why I never do it anymore. Did it once  
19 and that's it.

20 BY MR. SLATER:

21 Q. When mesh has to be removed, how does that  
22 analogy apply to the human body?

23 A. Well, I don't have the luxury of not being  
24 able to do that, like I can do with rebar concrete. It

1 is very similar. You have to cut, you have to use big  
2 scissors. We just did one two or three days ago, large  
3 scissors to cut through this. It's very stuck, and  
4 it's very tedious surgery because it can be fixed to  
5 the bladder, very difficult -- the bladder is thin, get  
6 into it, you got a mess. Posteriorly on the rectum or  
7 up top on the intestines, and you can't get it all out.  
8 It's a very tedious -- we call it a train wreck because  
9 it's very difficult to get out.

10 MR. ISMAIL: Objection, move to strike,  
11 nonresponsive, 403.

12 BY MR. SLATER:

13 Q. Doctor, with regard to the difficulty in  
14 removing the mesh, do you have an opinion as to whether  
15 or not that is medically safe or unsafe aspect of the  
16 Prolift® system?

17 A. It's quite unsafe.

18 Q. Doctor, with regard to the reaction of  
19 this large mesh implant that you've shown us with the  
20 human tissue, the foreign body reaction, the  
21 inflammatory response, do you have an opinion as to  
22 whether that is medically safe or unsafe?

23 A. It's unsafe.

24 Q. We're now, Doctor, going to go to some two



1 clips of video from actual surgical videos from Ethicon  
2 from their professional education department, correct?

3 A. That is correct.

4 Q. Now, have you reviewed and selected these  
5 short clips to help illustrate your opinions?

6 A. Yes, I have.

7 Q. Would they be helpful to you in  
8 demonstrating relative aspects of the Prolift®  
9 procedure?

10 A. Definitely.

11 Q. The first one that we're going to use is  
12 5701, and what we'll do is we'll show the video and  
13 while it's playing, please, just as you did before with  
14 the animations, narrate and tell us what is of  
15 significance to you in explaining your opinions on the  
16 Prolift®.

17 MR. ISMAIL: Objection, 403, to showing  
18 the video.

19 THE WITNESS: It's going to be a surgical  
20 video. It's going to be sort of graphic for  
21 people not used to this, but it's showing the  
22 mesh trying to be put through the vagina.  
23 They're doing actually a stay stitch there  
24 first. And now they've got the retrieval

1 devices already in there, and there they're  
2 actually stuffing the mesh in there, because,  
3 remember, I showed you the mesh, it's a large  
4 volume of mesh, the vagina is small. You have  
5 to stuff it in there. So that was actually a  
6 very good description or visual image for  
7 everybody to just kind of see how you have to  
8 push it through there.

9 BY MR. SLATER:

10 Q. When the mesh gets pushed in that way,  
11 what impact does that have on the mesh itself?

12 A. Well, there can be multiple different  
13 factors. You're pushing it through vagina, which can  
14 cause infection of it, contamination of it. You can  
15 distort the meshes if you're pulling on it, and it's  
16 not going to lay flat.

17 Q. Let's go to clip -- and one other thing,  
18 in that image, in that video there were -- did we see  
19 the cannulas actually coming out that were placed for  
20 an anterior procedure?

21 A. Yeah, we saw on that one the retrieval  
22 devices were already in. The cannulas had already been  
23 removed. The retrieval devices were there on the mesh  
24 arms, they hadn't been pulled through yet.

1 Q. Let me ask you this: In the image we  
2 could actually see the white cannulas. Were they still  
3 in the body, not the next clip, but the clip we just  
4 saw?

5 A. I thought the cannulas had been removed  
6 already. I'd have to look at it then. If the cannulas  
7 were removed, then just the -- yeah, the cannulas are  
8 still there, yes.

9 Q. Let's go to clip 5702, the next clip, and  
10 tell us as it plays what we're seeing and what's  
11 significant, please.

12 MR. ISMAIL: Objection, 403.

13 THE WITNESS: Okay. So now we see he's  
14 pulling out the cannula and then the mesh arms  
15 extending out through the obturator foramen,  
16 and, again, what's important to note about that  
17 as we saw earlier the size of the mesh arms,  
18 which are about one centimeter, a little larger  
19 going through those cannulas, which are just a  
20 couple millimeters and they're rolled, so it  
21 will cause the mesh to roll, the arm meshes to  
22 roll.

23 BY MR. SLATER:

24 Q. And what we'll do now is go to the next

1 PowerPoint slide, which is a side by side comparison of  
2 a still shot from the animation and from the video we  
3 just saw, and can you tell the jury what of  
4 significance this shows?

5 MR. ISMAIL: Objection, 403.

6 THE WITNESS: Okay. The biggest thing to  
7 me is if you look at the cartoon first, for me  
8 it's on the left, that the mesh arms are laying  
9 flat, but then, in reality, when it goes into  
10 the human, you can't have a 1 to 1.5 centimeter  
11 mesh arm go through a cannula that's a couple  
12 millimeters and not get it to roll. So if you  
13 were able to zoom in there where it comes out  
14 of the skin, it's going to be rolled. That's  
15 going to also collapse those pores and start  
16 that whole cascade of inflammation, foreign  
17 body reaction, scarring.

18 BY MR. SLATER:

19 Q. When the mesh is pulled through the  
20 cannulas, as we see illustrated on these still shots,  
21 what happens to the mesh when it's being pulled through  
22 the cannulas, what happens to the pores and the mesh  
23 itself?

24 A. It can collapse, it will collapse. If

1     you're pulling on it with more than, what, 2.3-kilos,  
2     which is roughly 12 pounds of force, which is not much,  
3     and you'll pull on it, those pores -- remember, they  
4     start like this, you pull on them and they'll collapse  
5     on you. Again, that increases the foreign body,  
6     prevents that growth through the interspaces and starts  
7     that whole foreign body cascade I talked about.

8             Q.     With regard to the amount of force you  
9     just stated, was that confirmed to be the amount of  
10    force used during the procedure by Scott Ciarracca?

11            A.     Correct.

12                   MR. ISMAIL:  Objection, lack of  
13                   foundation.

14    BY MR. SLATER:

15             Q.     Do you have an opinion -- and we can take  
16     that down now.

17                   Do you have an opinion, Doctor, as to whether  
18     or not the arms and the cannulas are necessary to treat  
19     pelvic organ prolapse?

20            A.     I have an opinion, yes.

21             Q.     What's your opinion?

22            A.     They're absolutely not essential.  They're  
23     counterproductive.

24             Q.     And do you have an opinion as to whether

1 or not the use of the arms and the cannulas, as we've  
2 seen, is medically safe or unsafe?

3 A. It's unsafe.

4 Q. Why is that?

5 A. Again, like I've mentioned, as far as just  
6 multiple different issues. Number one, the rolling  
7 going through the muscles, which will cause contraction  
8 and pain. Then also it fixes the vagina. The vagina  
9 is a dynamic organ. As a woman stands, lays down,  
10 coughs, it's going to move. Those arms are going to  
11 cause it to be fixed, and then so when she does  
12 activity, that's what causes the pain, so pull on the  
13 muscles and other structures.

14 Q. Let's go to the next PowerPoint slide. We  
15 have in front of you a slide we've titled tension free  
16 and, first of all, we have little footnotes there with  
17 respect to the deposition testimony where these pieces  
18 of information came from.

19 Have you read those depositions?

20 A. Yes, I have.

21 Q. And have you relied on those depositions  
22 in part in forming your opinions?

23 A. Yes.

24 Q. What is tension free? In the context of

1 Prolift® and the concept of the Prolift®, what was the  
2 concept of tension free?

3 A. Well, tension free, if we're talking about  
4 the mesh just sitting on the table versus the mesh in  
5 real life, okay, I deal with real life. I don't care  
6 what it's like on the table. I care what's in the  
7 patient.

8 So as it sits on the table, it's going to be  
9 tension free, there's no pulling on it. But in order  
10 for you to put it in the woman, it's impossible to have  
11 something be tension free. If there's no tension, the  
12 prolapse still exists, so it's -- you can't have it in  
13 real life in the patient.

14 Q. Now, the first thing we have on this, on  
15 documents, I'm just going to ask you about a phrase  
16 tension free, meaning the mesh is in unstretched  
17 condition as if laying on a table, okay.

18 Do you have an opinion as to whether or not in  
19 actual use in the body, the mesh can be placed tension  
20 free, as described there?

21 A. It cannot be.

22 Q. And just very simply why? I think you  
23 might have talked about this already, but just very  
24 simply.

1           A.     Again, like we've talked about that the  
2     human vagina is not a table, okay. It's going to be  
3     moving, lifting, walking, and it's going to -- in order  
4     to hold a prolapse, which is everything is falling  
5     down, you've got to hold it up; therefore, there's  
6     going to be tension on that device. Placing it through  
7     the body is going to require tension. You've got to  
8     pull it through and adjust it.

9           Q.     And we saw the video of how it was pushed  
10    through the vagina and then how the arms were used.  
11    Does that impact on that opinion as well?

12          A.     Again, that's consistent with my opinion.

13          Q.     Tension on the mesh plus contraction  
14    equals pain. What is the significance of that?

15          A.     That's what I referred to earlier, that if  
16    mesh is pulled with a minimal amount of force,  
17    12 pounds of pressure, those pores will collapse. That  
18    will cause this foreign body reaction, inflammation and  
19    scarring, that causes the mesh to contract, article  
20    like by Tunn, et al., 65, 80% mesh contraction. When  
21    that happens, structures are pulled on, specifically  
22    muscles or nerve intergrowth, and that causes pain.

23                 MR. ISMAIL: Objection, move to strike,  
24                 hearsay.



1 BY MR. SLATER:

2 Q. Doctor, look at the next exhibit on the  
3 pile. Take that slide down.

4 It's Exhibit P2227, and it's an e-mail written  
5 by Piet Hinoul, medical affairs director, September 3,  
6 2009.

7 Is this an e-mail you're familiar with?

8 A. Yes, it is.

9 Q. What I'd like to do is turn to the second  
10 page. There are a series of asterisked bullet points.  
11 We're going to go to the last one on the page, which  
12 starts there is an issue.

13 Do you see where I'm reading? It's the last  
14 asterisk.

15 A. I'm there, yes.

16 Q. I'm going to just read it for the record,  
17 and then I want to ask you about this, okay?

18 A. All right.

19 Q. "There is the issue of being able to  
20 adjust, fine tune the position of a Prolift® mesh.  
21 This must also be addressed up front; the mesh and  
22 Prolift® can indeed be adjusted, but that is because  
23 one overcorrects (surgeons not adjusting by loosening  
24 after having pulled it too tight have all the problems

1 with pain, incontinence, obstructed defecation), again  
2 we adjust to make it tension free not the other way  
3 around."

4 And then reading a little further, this tension  
5 free concept is something we own, we must also use it  
6 here. Doctors like the sound of it (despite the fact  
7 that most do not understand it).

8 Now, is that language I just read written by a  
9 medical affairs director, Piet Hinoul, of significance  
10 to you?

11 A. Yes.

12 Q. Why?

13 A. Well, they acknowledge multiple different  
14 things in here. Number one that surgeons don't know  
15 how to tension this, and, number two, the tension free  
16 concept is something that sounds very good. The  
17 company wants to protect that marketing aspect. That's  
18 a different story here, but the biggest one is that the  
19 surgeons don't know how to tension this.

20 MR. ISMAIL: Objection, move to strike,  
21 nonresponsive.

22 BY MR. SLATER:

23 Q. Let me ask you this question: I just want  
24 to clean something up in case -- that was a great

1 objection, just got to always hedge against that.

2 Doctor, this language that I just read, why  
3 is -- well, let me just say something right now. When  
4 you answer this question, don't talk about marketing at  
5 all, okay. So I'm going to ask the question again.

6 Doctor, I just read language written by Piet  
7 Hinoul, medical affairs director. Why is that language  
8 significant to you with regard to the tension free  
9 concept?

10 MR. ISMAIL: Objection, lack of  
11 foundation.

12 BY MR. SLATER:

13 Q. From a medical standpoint, why is that  
14 important?

15 A. From a medical standpoint, you know,  
16 again, multiple different aspects of the tendency of  
17 surgeons to tighten this up too much. They don't  
18 understand how to tighten this. It hasn't been  
19 explained to them well enough. And so -- and that  
20 tensioning problem is one of the root sources for all  
21 the various different complications, pain, obstruction,  
22 incontinence, et cetera.

23 Q. When the mesh is placed under tension, in  
24 your opinion, does that lead to any negative side

1 effects?

2 A. Yes.

3 Q. What is that?

4 A. Again, that's going back to this issue,  
5 it's the root source of the problem that tensioning  
6 causes the pores to collapse, can cause the tissue  
7 integration, which then leads to scarring, inflammatory  
8 response and subsequently pain.

9 Q. Doctor, we'll take that document down.

10 Doctor, there was a theory that this large mesh  
11 implant would result in a more durable, longer lasting  
12 anatomic repair than with a suture repair.

13 Was that part of the concept?

14 A. Correct.

15 Q. When we say the focus was on an  
16 anatomic -- correction, the anatomic positioning, what  
17 does that mean?

18 A. It means we have to kind of go back almost  
19 a certain step. When you have a woman with prolapse,  
20 it means the bladder or structure has fallen down to  
21 the wrong spot. So you have anatomy is can you restore  
22 it to a normal position, okay. So that's where we talk  
23 about anatomical repair, putting it back up to where it  
24 should be.

1           Q.    Now, over time I've seen reference to  
2   functional outcomes, quality of life outcomes.

3                   What does that mean?

4           A.    That's the other aspect of prolapse,  
5   just -- and it's a quality of life problem. Just  
6   because you have an organ that's fallen down, say the  
7   bladder, articles like Whiteside, et al. 2004 talk  
8   about what we're really after here is this woman's  
9   quality of life, is she happy, is the support, the  
10   surgery provided an improvement of quality of life.

11                   MR. ISMAIL:  Objection, move to strike,  
12                   hearsay.

13   BY MR. SLATER:

14           Q.    Doctor, I'm going to ask you the question  
15   again.  Don't refer to, in case the objection was well  
16   done, the Whiteside article in answering the question.

17                   MR. SLATER:  I assume that's your  
18                   objection, right?

19                   MR. ISMAIL:  Yes.

20                   MR. SLATER:  Okay.  Trying to move this  
21                   along.

22   BY MR. SLATER:

23           Q.    Doctor, when we talk about functional  
24   outcomes, quality of life outcomes as opposed to

1     anatomic, what's the distinction?

2             A.     Anatomy is just looking at has that  
3     prolapse been repaired or not. It's not taking into  
4     account a patient's quality of life, sexual function or  
5     just symptoms of prolapse, fullness, pressure.

6             Functional outcomes are looking at if you do  
7     this surgery is the woman pleased with the outcome as  
8     far as the improvement of the prolapse symptoms.

9             Q.     Doctor, please look at the next exhibit,  
10    which is PLT1093. This is an article titled "Incidence  
11    and risk factors for reoperation of surgically treated  
12    pelvic organ prolapse" authored by Dällenbach and some  
13    other authors in 2011.

14            Are you familiar with this article?

15            A.     Yes, I am.

16            Q.     Is this article, in your opinion,  
17    medically reliable and authoritative in the field?

18            A.     Yes, it is.

19            Q.     Is this an article you've relied on in  
20    forming your opinions?

21            A.     Yes.

22            Q.     Why is this article important, in general  
23    terms?

24            MR. ISMAIL: Objection, hearsay.

1 BY MR. SLATER:

2 Q. Rephrase. Why is this article of  
3 significance to you?

4 MR. ISMAIL: Objection, hearsay.

5 THE WITNESS: Because what it's doing is  
6 looking at and trying to correct somewhat of  
7 the incorrect thinking we have as far as the  
8 true recurrence rate and reoperation rate  
9 following prolapse repairs. So what this is  
10 doing is breaking it down and looking at the  
11 true incidence, which records it at roughly --  
12 I think their conclusion is like 6 to 12%  
13 reoperation for prolapse.

14 BY MR. SLATER:

15 Q. Doctor, if you turn to the page that has  
16 the discussion on it, I'm not seeing the page numbers.  
17 It's the third page from the end.

18 A. Okay, I'm there.

19 Q. And it says -- you see discussion?

20 A. Yes, I do.

21 Q. Okay. It says in the first sentence, our  
22 study suggests that the risk of reoperation after  
23 prolapse surgery is relatively low and associated with  
24 variables indicating pre-existing weakness of pelvic

1 floor tissues.

2 What is that -- is that of significance to you?

3 MR. ISMAIL: Objection, hearsay. Do I  
4 have a standing objection to Exhibit 1093?

5 MR. SLATER: You have a standing objection  
6 to every one of my articles as hearsay and any  
7 questions on them.

8 MR. ISMAIL: I understand, but I'm going  
9 to identify each one to which I have the  
10 hearsay objection, and then I won't interrupt  
11 your exam on this article.

12 MR. SLATER: Yeah, please don't.

13 MR. ISMAIL: Standing objection to 1093 on  
14 hearsay.

15 MR. SLATER: I'll start again.

16 THE WITNESS: And can you -- I'm trying to  
17 track exactly where you are.

18 BY MR. SLATER:

19 Q. You see Discussion?

20 A. Yes, I am under Discussion.

21 Q. Okay. I'm going to actually go now to the  
22 second paragraph. You see it says, "we  
23 systematically"?

24 A. Yes, I'm there.



1           Q.    I want to read this and ask you what, if  
2   any, significance this has to you.

3           We systematically searched Medline, (search  
4   terms: "reoperation for surgically treated/managed  
5   pelvic organ prolapse, recurrent pelvic organ prolapse,  
6   follow-up studies," all languages, from 1966 to 2010)  
7   and found few studies reporting the incidence of  
8   reoperation for recurrent prolapse. Most authors  
9   measured the combined risk of reoperation for  
10   surgically treated prolapse and urinary incontinence,  
11   thus overestimating the rate for pelvic organ prolapse  
12   reoperation alone. The risk of reoperation for  
13   prolapse or urinary incontinence of 29.2% frequently  
14   quoted as a reference in further studies results in a  
15   retrospective cohort study of 384 women. It goes on to  
16   talk about following them prospectively, and at five to  
17   ten years their reoperation rate was 13% and 17%. And  
18   then says the risk of re-operation for prolapse alone  
19   during a five-year follow-up was much lower (1.5%) in  
20   another study.

21           Do you see that?

22           A.    Yes, I do.

23           Q.    Is that of significance to you?

24           A.    Yes.

1           Q.   Why is that significant to you in forming  
2   your opinions?

3           A.   Number one, you cannot describe the  
4   reoperation of prolapse if you're also combining it  
5   with stress incontinence, they're two separate  
6   problems, okay. So it's going to falsely elevate both  
7   of them in reality, and so that's why they're talking  
8   about the common report of 29.2%, which I've actually  
9   rooted my studies, so it's not accurate. So what they  
10   did then is look at the true reoperation rate, and so  
11   for this one, you know, they are down to 1.5% at  
12   five-year follow-up, which is obviously a very small  
13   number.

14          Q.   Now, they're talking about treating  
15   patients with suture repairs, correct; that's what they  
16   did?

17          A.   That's correct.

18          Q.   Okay. Turn to the next page, please. And  
19   it's actually the second to last page of the article,  
20   there is a Table 6 at the top left corner, and if you  
21   come down that left column, about two-thirds of the way  
22   down the page, there's a sentence that says, "The  
23   anatomical recurrence rate in our cohort is probably  
24   higher; but, in most cases, women are asymptomatic and

1 do not require surgery."

2 Is that significant to you?

3 A. That is correct.

4 Q. Why?

5 A. Because, again, when you have -- this is a  
6 prolapse is a quality of life problem, okay. So what  
7 you want to do and what success is is the woman  
8 asymptomatic and her symptoms of prolapse cured. So  
9 they're saying as the anatomy may have come down, but  
10 the women are fine.

11 Q. On the right-hand column almost directly  
12 across the page, it says based on previous reports, we  
13 would expect a high right of reoperation, which is not  
14 the case. Our study supports the idea that  
15 conventional vaginal surgery is effective to treat  
16 pelvic organ prolapse.

17 Is that of significance to you?

18 A. Yes.

19 Q. Why?

20 A. Because it's showing that the traditional  
21 types of repairs actually work to relieve the patient's  
22 symptoms.

23 Q. And, finally, on the last page in the last  
24 paragraph, based on our data and recent studies, we

1 believe the risk of reoperation for recurrence after  
2 pelvic organ prolapse reconstructive surgery to be  
3 between 6% and 12% rather than 30% as previously  
4 described.

5 Is that significant?

6 A. Yes.

7 Q. Why?

8 A. Again, it's stating that the 29.2 or 30%,  
9 as they state here, reoperation rate is much higher  
10 than in reality, it's down to around 6 to 12%.

11 Q. Based on the Dällenbach article, your  
12 understanding of the overall medical literature, your  
13 experience and your knowledge in the field, do you have  
14 an opinion as to whether or not the Prolift® was  
15 necessary in order to treat pelvic organ prolapse as  
16 compared to the existing traditional alternatives?

17 MR. ISMAIL: Objection, hearsay,  
18 cumulative.

19 THE WITNESS: Based upon this study and  
20 others and my own personal experience, it was  
21 not needed.

22 BY MR. SLATER:

23 Q. Meaning that the alternatives were  
24 adequate?

1 A. Correct.

2 MR. ISMAIL: Objection, same, cumulative,  
3 sorry.

4 MR. SLATER: Go off for a second.

5 THE VIDEOGRAPHER: Off the record. The  
6 time is 10:32, we are off the record.

7 (Brief recess.)

8 THE VIDEOGRAPHER: The time is 10:41, and  
9 we are back on the record.

10 BY MR. SLATER:

11 Q. Doctor, in the course of asking you about  
12 your background, I neglected to ask you one question.

13 Are you a board certified physician?

14 A. Yes, I am.

15 Q. Who are you board certified by?

16 A. By urology, American Urologic Association  
17 and then also by combined boards of urology and GYN for  
18 female pelvic medicine and reconstructive surgery.

19 Q. And what is the significance of those  
20 board certifications?

21 A. The first one is stating that you have  
22 gone through -- for me it was six years of urologic  
23 training, including general surgery, and that the board  
24 recognizes you having taken three different exams that

1     you are a qualified urologist.

2             The second one is subspecializing in female  
3     urology and pelvic floor reconstruction, so the boards  
4     of GYN, urology came together because we have a lot of  
5     overlap, and I've had this certificate available since  
6     2013.

7             Q.     Okay. Doctor, we're now going to go to  
8     the next exhibit, which we've marked P0049, and if you  
9     could, first looking at the front page, what is this  
10    document?

11            A.     This is just the -- as it states at the  
12    top, the Evaluation of the TVM technique for Ethicon.

13            Q.     It says clinical study report dated  
14    June 27, 2006, and it says the principal investigator  
15    was Michel Cosson, Dr. Cosson. Is that what this  
16    technically is, is this clinical study report for the  
17    French TVM study?

18            A.     That is correct and their 12-month data.

19            Q.     And let's now turn to Page 4. There's a  
20    section that says -- and just very, very briefly and  
21    simply, what was the French TVM study; what were they  
22    doing?

23            A.     They were looking at the feasibility and  
24    the results and the complications, efficacy of the TVM

1 technique.

2 Q. And when you say the TVM technique, that's  
3 what ultimately became the Prolift® procedure?

4 A. That is correct, yes.

5 Q. And we look at the statistical methods  
6 section, and I'm going to try to avoid much of the  
7 statistical jargon and let you explain it simply, but  
8 about six or eight lines down, there's a sentence that  
9 says, the criterion for success was that the upper 90%  
10 two-tailed confidence interval (same as the tail on a  
11 one tail 95% confidence interval) did not exceed 20%.  
12 Otherwise, the study would be deemed a failure, as it  
13 would not show that the prolapse rate was less than  
14 20%.

15 In layman's terms, what is that telling us?

16 A. Any time you set up a study you establish  
17 criteria beforehand of what you expect is defining as  
18 success, so they're doing a very good job of that.

19 Then they get into a bunch of statistical  
20 stuff, the two-tailed confidence interval, et cetera.  
21 It's detailed statistics of how they prove something is  
22 a success or not, and then their bottom line saying  
23 that if they have a prolapse recurrence greater than  
24 20%, that they deemed the procedure as a failure.

1           Q.    And when they see -- well, I'll withdraw  
2    it.  Let me move forward.  Let's go down to the results  
3    and conclusions section, the actual results now.  It  
4    says, the primary effectiveness variable was recurrence  
5    of prolapse at 12 months post-procedure (failure of  
6    procedure), with failure being defined as a prolapse of  
7    International Continence Society Stage II or more or a  
8    surgical re-intervention.

9           So that's telling us the criteria for success  
10   or failure?

11          A.    Again, they're going on -- they're  
12   defining what we define, the studiers, the researchers  
13   as a success or failure.  So they're saying the  
14   International -- ICS, International Continence Society  
15   Stage II or more or surgical re-intervention is  
16   failure.

17          Q.    When they say recurrence of prolapse, does  
18   that just mean after you've treated it does it come  
19   back at some level?

20          A.    Correct, that's anatomic recurrence, yes.

21          Q.    And they call Stage II being a recurrence.  
22   What does that mean?

23          A.    That just means that you grade prolapses.  
24   There's multiple different grading systems, but you



1 grade them. Easiest way is grade 1 is essentially  
2 completely normal. Grade 2 is little bit of prolapse,  
3 grade 3 is more, grade 4 is coming all the way out.  
4 That's just a brief way of describing it. So they're  
5 saying Stage II where it's dropped down a fair bit is a  
6 failure.

7 Q. I'm reading now further in the results and  
8 conclusions section. The results show a failure rate  
9 at 12 months of 18.4% with a 90% confidence interval of  
10 -- I'm going to start over.

11 I'm going to read now within the results and  
12 conclusions section. The results show a failure rate  
13 at 12 months of 18.4% with a 90% confidence interval of  
14 11.9 to 26.6. Thus the study did not meet the  
15 predefined criteria of a failure rate of less than 20%.

16 What does that mean?

17 A. It means that at 12 months, which is the  
18 absolute minimum you would want to do a study for  
19 prolapse, 12 months would be very, very minimum, that  
20 based upon the statistical analysis they were above the  
21 20% predefined failure rate. So, subsequently, based  
22 upon this data, the TVM system, which became Prolift®  
23 did not make anatomical success, did not reach their  
24 criteria.

1 Q. And just to be clear, they gave a range of  
2 11.9 to 26.6, that's the confidence interval where  
3 they're saying we can take these results and apply them  
4 more broadly, and that's the statistical range?

5 A. Correct. That's when statistics --  
6 advanced people with biostatistics come in and do their  
7 math, and so I have to trust their math on that one.  
8 So they're telling me it did not meet the success of  
9 the procedure.

10 Q. The second paragraph of the results and  
11 conclusions says the secondary effectiveness parameters  
12 show a failure rate at six months of 12.6%, 90%  
13 confidence interval, 7.3 to 20.1%.

14 What is that telling us?

15 A. Again, they're just saying at the short  
16 term at six months, the raw number of 12.6 had already  
17 recurred, so it was a fast recurrence.

18 Q. And the 20.1% with the confidence  
19 interval, it was already over 20%?

20 A. Yes, I'm sorry. Yes, at six months  
21 already they had exceeded their predefined success or  
22 failure number.

23 Q. Turn to Page 5, please, the very top of,  
24 again, the results and conclusions section, moderate or

1 severe vaginal retraction was reported in 11 (12.6%)  
2 patients.

3 What is that telling us?

4 A. Vaginal retraction is what we've already  
5 mentioned earlier on scarring of the mesh. They happen  
6 to use the word retraction. It's the same thing, but  
7 in these surgeon's hands, high volume surgeons, they  
8 had 12.6 of moderate or severe contraction, mesh  
9 contraction.

10 Q. Based on the results of the TVM study, do  
11 you have an opinion as to whether or not the Prolift®  
12 was a safe and effective procedure to be marketed on  
13 the widespread basis it was?

14 A. Let's break it down in two. You said safe  
15 and effective. So, number one, effective, no. These  
16 researchers, it failed. It did not meet the  
17 effectiveness, which is purely anatomic.

18 Safety-wise, that was addressed in the second  
19 one, that 12.6, so not a small number, had vaginal  
20 retraction that was visible or palpable.

21 So on both those aspects, no.

22 Q. Did you see Axel Arnaud's deposition  
23 testimony where he testified that the French TVM study  
24 showed a 20.7% exposure rate at one year?

1 MR. ISMAIL: Objection, leading, lack of  
2 foundation.

3 THE WITNESS: Yes, I read that.

4 BY MR. SLATER:

5 Q. Is that of significance to you?

6 A. Very much so, yes.

7 Q. Why?

8 A. Because he stated what the true incidence  
9 of the vaginal mesh exposure was in the study at 20.7,  
10 which the study itself quotes a lower number.

11 MR. ISMAIL: Objection, lack of  
12 foundation.

13 BY MR. SLATER:

14 Q. Is a 20.7% exposure rate, in your opinion,  
15 a safe rate for that complication?

16 A. No.

17 Q. Why not?

18 A. Well, not just my opinion, my colleagues,  
19 internal documentation say, you know, that is a very  
20 common number. It is a very high number, and that  
21 ultimately leads to reoperation, which is increased  
22 risks there, so, no, it's not a safe number.

23 Q. Okay. Let's go to the next PowerPoint  
24 slide. I want to ask you about design challenge is a

1 controlled foreign body reaction, and we cite to Piet  
2 Hinoul.

3 Do you have an opinion as to whether or not the  
4 Prolift® achieved the design challenge of a controlled  
5 foreign body reaction in women?

6 MR. ISMAIL: Objection to the use of the  
7 slide.

8 THE WITNESS: It did not.

9 BY MR. SLATER:

10 Q. And what's your basis for that?

11 A. The basis is going to be multifactorial.  
12 My personal experience day-to-day examining patients,  
13 operating on patients, review of the medical  
14 literature, a review of internal documentation,  
15 attendance at national, international meetings,  
16 discussion with colleagues, that the mesh did not have  
17 a controlled foreign body reaction and had  
18 complications associated with it.

19 BY MR. SLATER:

20 Q. The concept of a fine balance, if there's  
21 too much fibrosis, it would be unsafe, as testified to  
22 by Piet Hinoul.

23 Do you have an opinion as to whether or not the  
24 Prolift® achieved that fine balance?

1 MR. ISMAIL: Objection, argumentative,  
2 705.

3 THE WITNESS: It did not meet that fine  
4 balance.

5 BY MR. SLATER:

6 Q. And what's your basis for that opinion?

7 A. Again, just like I just mentioned, all  
8 those aforementioned criteria. No small issue is my  
9 daily or weekly examination of patients with Prolift®,  
10 medical literature, review or our attendance at  
11 meetings, international, national colleagues,  
12 discussing those issues.

13 Q. And with regard to the concept of too much  
14 fibrosis would be unsafe, why is that? I think you've  
15 talked about it, but let's just make it clear for the  
16 record right now.

17 A. Again, fibrosis is a response to the mesh  
18 and the decrease in pore size, the small pore size,  
19 which causes foreign body reaction, chronic  
20 inflammation, which the body responds naturally, just  
21 causing scarring.

22 So too much fibrosis is a result of all those  
23 other issues, okay, come together, and that's what  
24 causes the pain, the vaginal extrusion, et cetera.

1 Q. There's a concept of scar plating or  
2 bridging fibrosis. You may have -- I think you talked  
3 about it earlier, but is that relevant in this context?

4 A. Yes, that's what I'm referring to, the  
5 scar plating is the result of the implantation of the  
6 device, the decreased pore size, inflammation, foreign  
7 body reaction, more scarring, and then you get that  
8 plate. Remember, I keep going like this. This is  
9 where it goes -- theoretically goes through the tissues  
10 versus plating and scarring.

11 Q. Let's go to the next PowerPoint slide.

12 With regard to the concept of design  
13 requirements, are you familiar with testimony from  
14 Ethicon witnesses about their design requirements?

15 MR. ISMAIL: Objection as argumentative,  
16 use of the slide, leading, lack of foundation.

17 THE WITNESS: Yes, I've read all those  
18 depositions.

19 BY MR. SLATER:

20 Q. I want to ask you about a specific design  
21 requirement. The mesh lays flat. Assuming that the  
22 mesh laying flat is a design requirement for the  
23 Prolift®, do you have an opinion as to whether or not  
24 the Prolift® met that design requirement?

1 A. It did not meet that requirement.

2 Q. And what's your basis for that?

3 A. Okay. Basis, again, goes down the line of  
4 my physical exam of these patients on a weekly basis,  
5 including those with Prolift®, the medical literature,  
6 internal documentation, national/international  
7 meetings, discussion with colleagues.

8 Q. With regard to whether the mesh lays flat,  
9 we've seen some materials and some videos here today,  
10 does that enter into your opinion on that?

11 A. Yes.

12 Q. Why is that?

13 A. The mesh, the Prolift® kit, when the mesh  
14 comes it's a one size fits all, okay. It's analogous  
15 to saying everybody should fit in the same size of  
16 shoe, doesn't happen. So if that mesh is, let's say,  
17 this long and you have a woman who is shorter or the  
18 surgeon does not place it in the correct location or  
19 the sufficient location, that mesh is going to bunch  
20 up, it's not going to lay flat. It can't.

21 Q. With regard to the arms and the use of the  
22 cannulas, does that impact on your opinion?

23 A. Yes, see, the arms, see, that's also  
24 another aspect, the arms are going to be pulling on



1 this. The pelvis is a dynamic structure, okay. It's  
2 not just like always laying down at the time of  
3 surgery. A woman is going to be getting up, she's  
4 going to be moving, she's going to go right, she's to  
5 go left, she's going to lean over, and that's going to  
6 make the vagina have to move.

7 The pelvis is an incredibly complicated  
8 structure, and so these internal organs have to move.  
9 Now if they're anchored in and have these arms going  
10 out, going through muscles and that's anchored in  
11 because of the scarring, foreign body reaction, et  
12 cetera, it can't do that. So when those mesh arms  
13 pull, it's going to be causing the pain and also the  
14 vaginal extrusion and other factors -- other issues,  
15 excuse me.

16 Q. When the mesh arms came through the  
17 cannulas and they come through the cannulas in the  
18 body, are they flat or has the shape been changed?

19 A. No, just like I pointed out, that's why  
20 the video was so important, that's why I said the  
21 original cartoon is not fair because it shows them  
22 laying flat. You cannot have a flat piece of mesh this  
23 wide go through a cannula -- a cannula this big, you  
24 can't have a one centimeter thing come out flat, it

1     won't be, can't do it, physically impossible.

2             Q.     Okay. A design requirement of the mesh  
3     incorporated safely into the woman's pelvis.

4             Assuming that to be one of the design  
5     requirements, do you have an opinion as to whether that  
6     design requirement was met with the Prolift®?

7             A.     It was not met.

8             Q.     Why is that?

9             A.     Again, that goes back to everything we've  
10    said over and over. The mesh has to be safely  
11    incorporated in the pelvis, so no scarring, no  
12    extrusion, no fibrosis, no pain, and that was not  
13    achieved.

14            Q.     Doctor, we're going to take that slide  
15    down. We're going to go to the next exhibit. Please  
16    look at Exhibit PLT0067 titled "Complications from  
17    vaginally placed mesh in pelvic reconstructive  
18    surgery."

19            Are you familiar with this article?

20            A.     Very much so, yes.

21            Q.     Is this article, in your opinion,  
22    medically reliable and authoritative in the field?

23            A.     Yes, it is.

24            Q.     Is this an article that you've relied on

1 in forming your opinions?

2 A. Yes.

3 Q. Okay. What is this article?

4 MR. ISMAIL: Objection, hearsay.

5 THE WITNESS: This is written with my  
6 colleagues in the urogynecology department at  
7 Mayo. Roberta Blandon, she was a resident. I  
8 didn't know her, but I know Gebhart, Trabuco  
9 and Klingele well. I operate every other week  
10 with three of -- two of those.

11 And so this is summarizing -- this is in  
12 the very early days, it was published in 2009,  
13 submitted I think probably prior to that in the  
14 early days of the mesh complications. It's one  
15 of the first papers out there talking about  
16 those complications.

17 BY MR. SLATER:

18 Q. And I just want to ask you a question  
19 because we're going to talk a little bit more about the  
20 complications described in this paper. Rephrase.

21 I want to ask you something baseline before we  
22 talk about -- rephrase.

23 I want to ask you a baseline question.

24 When contracted Prolift® mesh is explanted,

1     when that's being done and when it's taken out, what  
2     is -- we've seen what it looks like out of the box and  
3     how it feels. How is it -- is it any different when  
4     you're actually removing it from the body?

5             A.     It's a mess.

6             Q.     What do you mean by that?

7             A.     It's a very difficult surgery. The  
8     mesh -- there is actually a picture of explanted mesh  
9     here. Here we go.

10            The picture that they show on Page 529 is  
11     explanted mesh, okay. I, as a surgeon, look at this  
12     and that is a human's body attached to that mesh. They  
13     had to use big scissors to cut through this, and you  
14     look at the burned edges, that means they're using a  
15     cautery to burn through this mesh, okay. That is mesh,  
16     just like the analogous to the rebar, okay, rebar in  
17     concrete, okay. You got to get that out of there.  
18     It's a train wreck. You have to use a jackhammer to  
19     get it out. Obviously, in the human body you don't  
20     have to use that, but it's stuck in there because this  
21     is caked in scar.

22            MR. ISMAIL: I'm sorry. Move to strike,  
23            hearsay, 403, nonresponsive.

24     BY MR. SLATER:

1           Q.    Is the mesh soft when it's coming out when  
2    you're taking it out from these complications, or does  
3    it have -- what does it feel like?

4           A.    It's encased in scar, you can feel it.  If  
5    you want to say a nice thing about mesh is when you can  
6    feel it, because it's firm in there, okay.  Normal  
7    human body, it's not firm, okay.  And so when you try  
8    and get rid of autologous slings, they're very actually  
9    difficult to find, but the meshes you can rub back and  
10   forth, I tell the residents, I say, feel right here  
11   because a lot of times we're working deep down in the  
12   pelvis.  We can't see it.  You have to go by  
13   proprioception, feel this, feel this band, feel where  
14   this is going through the obturator foramen.  So, no,  
15   it's not soft at all.

16           Q.    Let's go to Page 529 of this article, and  
17    in the left-hand column, the second full paragraph, I  
18    want to read a sentence, a short portion of it, and ask  
19    you a question.  "One of our most important findings is  
20    that only 14% of patients were referred by the original  
21    surgeon, which suggests a lack of awareness of these  
22    complications by the original treating physician and  
23    the potential for underreporting of the rate and extent  
24    of these complications due to nonrespondent/volunteer

1 bias."

2 Is that significant to you?

3 MR. ISMAIL: Objection, hearsay.

4 THE WITNESS: Yes.

5 BY MR. SLATER:

6 Q. Why?

7 A. This mirrors my practice. Let's just  
8 focus on this data here, but the majority, especially  
9 in here, of these patients are not being referred by  
10 their doctor back home. Their doctor back home is  
11 unaware of the level and the severity of the  
12 complication, and the patient is seeking care  
13 elsewhere, which, again, that mirrors my practice.

14 MR. ISMAIL: Again, I assume we have a  
15 standing objection on Plaintiff Exhibit 67 use  
16 of hearsay.

17 MR. SLATER: You have your standing  
18 hearsay objection.

19 MR. ISMAIL: Thank you.

20 BY MR. SLATER:

21 Q. Let's go to the top of page -- of the  
22 right hand column on Page 529, about four lines down.  
23 I want to read the sentence and ask you a question or  
24 two sentences.

1           With the growing popularity of mesh insertion  
2   kits, in which a large surface area of synthetic  
3   material is placed, the vaginal surgeon is faced with  
4   the challenges of very complex surgical dissections.  
5   If mesh excision is warranted, tissue fibrosis,  
6   scarring, bleeding, and urinary tract and anorectal  
7   injury are easily encountered, which add to patient  
8   morbidity.

9           Is that of significance to you?

10          A.    Yes.

11          Q.    Why?

12          A.    Well, that mirrors my weekly practice.  
13   This is complicated surgery. You have arguably three  
14   of the top urogynecologists in the nation, there's  
15   going to be others who are good, but these are top  
16   notch guys, highly experienced at a high volume  
17   tertiary care center, and they're saying they struggle  
18   to do this. I struggle when I'm getting these things  
19   out. It's a bear.

20          Q.    Let's go to the bottom of that column, the  
21   right-hand column on Page 529. I want to read a  
22   sentence and ask you a question.

23                "It is important to remember that a percentage  
24   of patients who undergo pelvic reconstructive surgery

1 with vaginally placed mesh will have life-changing  
2 complications. Moreover, whereas minor complications  
3 such as small vaginal mesh erosions are simple and easy  
4 to manage, incapacitating pelvic pain, dyspareunia, and  
5 large-scale erosions can be exceedingly complex and not  
6 easily resolved."

7 Is that significant to you?

8 A. Yes, it is.

9 Q. Why is that?

10 A. Well, again, there's a focus on the  
11 vaginal extrusion, which the data from other  
12 individuals would say that is a much more recurrent  
13 problem than we knew at this point in time, but we're  
14 saying these are some life-changing, severe,  
15 life-altering problems that occurs as a result of the  
16 Prolift® mesh.

17 Q. And this article, the description of these  
18 various complications, in your opinion, do they apply  
19 to the Prolift®?

20 A. Absolutely.

21 Q. I want to go to the bottom of the first  
22 full paragraph on Page 530, the last sentence. This  
23 was February 2009, correct?

24 A. Correct.



1           Q.    "The widespread marketing of these  
2   technologies should be avoided until level I evidence  
3   becomes available demonstrating their superiority over  
4   traditional repairs, with acceptable rates of  
5   morbidity."

6           Is that significant to you?

7           A.    Yes, it is.

8           Q.    And why is that?

9           A.    They're stating here that basically this  
10   product is out without high quality studies showing  
11   that it's worked and it's safe, and they're saying it  
12   should not have been accepted, it should not be  
13   performed.

14          Q.    With regard to the Prolift®, do you have  
15   an opinion as to whether what I just read is accurate?

16          A.    It is accurate, yes, I support it  
17   completely.

18          Q.    Did they -- did Ethicon have level I  
19   evidence demonstrating superiority of the Prolift® over  
20   traditional repairs with acceptable rates of morbidity  
21   before it was marketed, in your opinion?

22          A.    There were no studies, no.

23          Q.    Did such studies ever exist, in your  
24   opinion, level I evidence showing the superiority of

1 the Prolift® over traditional repairs with acceptable  
2 rates of morbidity, was that ever produced for the  
3 Prolift®?

4 A. No. There are studies out there showing  
5 efficacy, anatomical success, but we've already talked  
6 about that. That's not quality of life. So to answer  
7 your question specifically, no, that has not been done.

8 Q. Let's go to the next PowerPoint slide.

9 Doctor, I want to ask you about testimony from  
10 David Robinson where he testified that gynecology had  
11 not adopted the routine use of meshes due to  
12 unacceptably high mesh complication rates.

13 Are you familiar with that testimony?

14 A. Yes, I am --

15 MR. ISMAIL: Objection, argumentative,  
16 lack of foundation.

17 BY MR. SLATER:

18 Q. David Robinson, who was the medical  
19 affairs director, listed what he perceived to be  
20 unacceptably high mesh complication rates, 6 to 25%, 3  
21 to 12% and 6 to 12% from various studies.

22 Are you familiar with that?

23 A. Yes.

24 MR. ISMAIL: Sorry. Objection to the use

1 of the slide, 403, argumentative.

2 BY MR. SLATER:

3 Q. With regard to the use, the routine use of  
4 meshes and the nature of the complications one sees  
5 with the Prolift®, do you agree or disagree with the  
6 medical affairs director that these types -- these  
7 rates of complications with the Prolift® whether that  
8 would be acceptable or unacceptable?

9 MR. ISMAIL: Same objection.

10 BY MR. SLATER:

11 Q. You can answer.

12 A. I have yet to answer any of the questions  
13 yet.

14 Q. You can answer.

15 A. Yes, I am familiar with this document,  
16 these are the depositions which I read, so I am very  
17 familiar with this, and I agree with him that the -- it  
18 has not been accepted due to high complication rates,  
19 and these are the numbers that he quoted.

20 Q. Let's go to the next slide.

21 Doctor, we have a PowerPoint slide here  
22 entitled "Prolift® TVM Complication Rates."

23 What is this showing us?

24 MR. ISMAIL: Objection, hearsay.

1 THE WITNESS: These are multiple different  
2 studies, I reviewed all of these studies.  
3 They're listed here. There are some --

4 BY MR. SLATER:

5 Q. Let me ask you -- let me stop you. These  
6 studies, are these studies medically reliable and  
7 authoritative in the field?

8 A. Yes, these are good quality studies.

9 Q. And did you rely on them for forming your  
10 opinions in this case?

11 A. Yes, I did.

12 Q. Okay. Go ahead, tell us what we're seeing  
13 here.

14 MR. ISMAIL: Objection, hearsay.

15 THE WITNESS: Basically, these are a  
16 combination of all the complications reported  
17 in these various different studies from these  
18 various different surgeons, going from as low  
19 of 15.6 to up to 33.6.

20 BY MR. SLATER:

21 Q. Now let's go to the next slide. Where we  
22 have side by side the rates of complications David  
23 Robinson had described as unacceptable versus the rates  
24 of complications for various studies of the Prolift®.

1           Why did you want to have this slide put  
2   together comparing these rates?

3           MR. ISMAIL: Objection, hearsay to slides  
4   15 and 16.

5           THE WITNESS: I put them in here  
6   specifically because David Robinson, a person  
7   of authority within Ethicon, had stated various  
8   different unacceptable rates as listed there  
9   from 3% up to 25%, as it states, and then we  
10   compare it to the available literature of these  
11   selected articles of stating complication rates  
12   much higher than that.

13 BY MR. SLATER:

14           Q. Do you have an opinion when you look at  
15   the rates of complications for these various studies of  
16   the Prolift® whether or not those rates are acceptable  
17   from a medical safety standpoint or not, in your  
18   opinion?

19           A. From my opinion, based upon my daily  
20   experience or weekly experience with these individuals  
21   is that each one of those complications represent a  
22   human being's life who has potentially been devastated,  
23   so these are unacceptable rates.

24           Q. And do you base your opinion also on your

1 reading of that literature and other associated  
2 literature?

3 A. These are just six to eight selected  
4 articles. There's many more articles -- and that's  
5 also not including my attendance at national,  
6 international meetings about this exact subject or --  
7 and lecturing on them.

8 MR. ISMAIL: Objection, move to strike,  
9 hearsay.

10 BY MR. SLATER:

11 Q. Let's go to the next exhibit, take the  
12 PowerPoint down. PLT0108, the next exhibit.

13 Doctor, I provided you Exhibit PLT0108. This  
14 is an article by various doctors, including Dr. Cosson.

15 Is this an article that you have relied on for  
16 your opinions?

17 A. Yes, I have.

18 Q. And is this article, in your opinion,  
19 medically reliable and authoritative?

20 A. Yes, it is.

21 Q. And this was dated as an accepted date of  
22 July 25, 2005, just a few months after the Prolift®  
23 went on the market?

24 A. Correct.

1 Q. And, again, Cosson, he's the one who was  
2 named in the final study report for the TVM study, he  
3 was the lead investigator for the Prolift® prototype  
4 study?

5 A. That is correct, yes.

6 Q. If we look in the abstract section in the  
7 beginning, about halfway down that abstract, they say  
8 that 34 cases of mesh exposure were observed within the  
9 two months following surgery, which represents an  
10 incidence of 12.27%.

11 Do you see that?

12 A. Yes, I do.

13 MR. ISMAIL: Objection, hearsay, standing  
14 objection to 108, please.

15 MR. SLATER: Yeah, you have a standing  
16 objection to them all.

17 MR. ISMAIL: I know, but I feel like I  
18 have to identify which ones are the  
19 inappropriate hearsay for the record.

20 MR. SLATER: No problem. You don't have  
21 to object again to this article.

22 THE WITNESS: Yes, I do, I see that.

23 BY MR. SLATER:

24 Q. Now, what I'd like to do is turn to the

1 last page -- before I do that, just for the record, you  
2 may have talked about it before, what is mesh exposure?

3 A. Mesh exposure, I have to be very careful  
4 on the nomenclature, good you point that out, mesh  
5 exposure now is defined as mesh that's coming through  
6 the vagina. If you look back at older report, they may  
7 talk about mesh erosion. Now mesh erosion is reserved  
8 for when mesh is eroding into another organ, bladder,  
9 rectum or somewhere else.

10 Q. That's a strict definition you apply in  
11 your clinical and academic practice, correct?

12 A. That is correct, yes.

13 Q. Do people still interchangeably use those  
14 terms?

15 A. Routinely the terms are used  
16 interchangeably, but in academic presentations and in  
17 papers now, it's very well-defined.

18 Q. Looking at the last page, the conclusion  
19 to the article written by -- the last author listed is  
20 the senior author, that would be Cosson, right?

21 A. Correct.

22 Q. Looking at the conclusion, the last  
23 paragraph, I want to read something and ask you a  
24 question about it.



1 "Nowadays, based on these data, we can only  
2 advise that caution be exercised when carrying out this  
3 new surgical procedure. In fact, experimental studies  
4 and clinical trials seem necessary in order to reduce  
5 the level of exposure to less than 5% of cases."

6 Is that statement of significance to you?

7 A. Very much so, yes.

8 Q. Why is that?

9 A. Well, because you have one of the  
10 highest -- at this point in time, one of the highest  
11 volume surgeons, Dr. Cosson, who is involved in the  
12 original studies of this, who knows it probably better  
13 than most -- well, much greater than most surgeons, and  
14 he, in his opinion, is saying that we have -- are  
15 having basically an unacceptably high complication  
16 rate. This should be reserved as an experimental  
17 procedure, meaning not widely accepted, until we can  
18 get that exposure rate down to he says 5%.

19 Q. Was the exposure rate across the board in  
20 general in the medical community, when you look at the  
21 medical literature, ever brought below 5% for the  
22 Prolift®?

23 MR. ISMAIL: Objection, hearsay.

24 THE WITNESS: No.

1 BY MR. SLATER:

2 Q. We had gone through an exhibit just a few  
3 minutes ago listing exposure rates for various Prolift®  
4 studies. Were they below or above 5%?

5 MR. ISMAIL: Objection, hearsay.

6 THE WITNESS: All those are above, and any  
7 studies I've ever reviewed which hint at lower,  
8 they're always short-term studies.

9 BY MR. SLATER:

10 Q. Let's go to the next exhibit.

11 Doctor, I've handed you what we've marked as  
12 Exhibit PLT0011. It's an a ACOG Practice Bulletin with  
13 regard to Clinical Management Guidelines for  
14 Obstetricians-Gynecologists, February 2007, and it says  
15 in the left column it was authored with the assistance  
16 of Dr. Scott Smilen and Dr. Anne Weber.

17 Are you familiar with this document?

18 A. Yes, I am.

19 Q. Is this something you've relied on for  
20 your opinions?

21 A. Yes, I have.

22 Q. Do you find this to be medically reliable  
23 and authoritative in the field?

24 A. Yes.

1 Q. I want to now draw your attention in this  
2 practice guideline, this is just -- these are  
3 recommendations to gynecologists in day-to-day practice  
4 for things they should consider and how they should  
5 practice routinely?

6 A. Correct. It's a bulletin that ACOG, which  
7 is the American College of OB-GYN puts out periodically  
8 on a routine basis of just updates for people to get a  
9 synopsis of what's going on.

10 Q. If you look at Page 468, the top  
11 right-hand portion, the last -- the first full  
12 paragraph in the right column, I'm going to read it and  
13 ask you a question.

14 MR. ISMAIL: Before do you, standing  
15 objection as hearsay to Exhibit -- Plaintiff  
16 Exhibit 11.

17 MR. SLATER: You have a standing or a  
18 sitting objection.

19 MR. ISMAIL: Thank you.

20 BY MR. SLATER:

21 Q. I'm going to read the first full paragraph  
22 in the right-hand column on Page 468.

23 "Given the limited data and frequent changes in  
24 the marketed products (particularly with regard to type

1 of mesh material itself, which is most closely  
2 associated with several of the postoperative risks,  
3 especially mesh erosion), the procedures should be  
4 considered experimental and patients should consent to  
5 surgery with that understanding."

6 Is that significant to you?

7 A. Yes.

8 Q. And why is that?

9 A. That this -- the ACOG board following  
10 review of the literature, has come with the opinion  
11 that the procedure is experimental, which means it  
12 should not be used in widespread for every patient.

13 Q. Do you have an opinion as to whether or  
14 not the Prolift® should or should not have been  
15 considered and actually utilized as an experimental  
16 procedure?

17 MR. ISMAIL: Objection, cumulative.

18 THE WITNESS: I have an opinion and it  
19 should have stayed as an experimental.

20 BY MR. SLATER:

21 Q. When something is experimental, what does  
22 that mean?

23 A. Experimental puts it in a completely  
24 different class of surgeries. The standard anterior

1 colporrhaphy, the traditional repair is not  
2 experimental. A procedure that is experimental means  
3 that it has not been proven safe and efficacious. It  
4 has to be both, can't just be one or the other, and so  
5 until it is proven safe, it cannot be for every surgeon  
6 to be doing it. It has to be under very close study  
7 guidelines with a highly informed and consented  
8 patient.

9 Q. Are you familiar with the fact that later  
10 in 2007, ACOG modified the bulletin to remove the word  
11 experimental?

12 A. Yes, I read that.

13 Q. Do you know why that was done?

14 MR. ISMAIL: Objection, first, relevance,  
15 403, lack of foundation.

16 THE WITNESS: I have read the internal  
17 documentation e-mails of how that came about,  
18 yes.

19 BY MR. SLATER:

20 Q. In very simple terms, what happened?

21 MR. ISMAIL: Same objection, also improper  
22 expert testimony, doesn't aid the jury.

23 THE WITNESS: There was pressure put on  
24 the ACOG bulletin, the committee that does

1           this, by individuals paid by Ethicon to  
2           change -- get rid of the experimental.

3   BY MR. SLATER:

4           Q.   Do you have an opinion as to whether or  
5   not the word experimental should have remained in that  
6   bulletin or not?

7           MR. ISMAIL:   Same objections.

8           THE WITNESS:   Absolutely should have.

9   BY MR. SLATER:

10          Q.   Should have remained?

11          A.   Should have remain -- absolutely, it  
12   should have remained there as experimental.

13          Q.   Let me ask you a question, we just saw an  
14   ACOG bulletin in February 2007 saying that these mesh  
15   kit procedures should be experimental.

16          Is that the same thing that Cosson, the  
17   developer of the procedure, said in 2005?

18          MR. ISMAIL:   Objection, leading.

19          THE WITNESS:   That is what he stated, yes.

20   BY MR. SLATER:

21          Q.   Let's go to the next exhibit, and it is an  
22   article that we've marked as PLT0139.

23          Is this an article that you are familiar with?

24          A.   Yes, sir.

1 Q. Is this an article that you believe to be  
2 medically reliable and authoritative?

3 A. Yes, as it pertains to the abstract. The  
4 remainder of the article is in French, so I have read  
5 it and I can (speaking in French), I can read a bit,  
6 but I can't read in detail here.

7 Q. With regard to the English abstract on the  
8 second page, is that medically reliable and  
9 authoritative?

10 A. Yes.

11 Q. And that's something you relied on for  
12 your opinions?

13 A. Definitely, yes.

14 Q. And this was written by various doctors  
15 from the TVM group, including Cosson?

16 A. Yes.

17 Q. And let's look at the abstract, let's look  
18 at the summary of the study they did?

19 MR. ISMAIL: Standing objection, hearsay,  
20 Plaintiff Exhibit 139.

21 MR. SLATER: Standing objection.

22 MR. ISMAIL: Thank you.

23 BY MR. SLATER:

24 Q. And what I want to do is go through this

1 in the first sentence, actually, the second sentence,  
2 it says, "In light of the growing number of proposed  
3 techniques and materials we reviewed the experience of  
4 the pioneers in order to provide surgeons with the most  
5 objective information available," and they're talking  
6 about the use of transvaginal mesh?

7 A. Correct.

8 Q. In the body of the article, they talk  
9 about certain complication rates with the use of  
10 synthetic mesh to treat prolapse, and about halfway  
11 down it says, "The rate of erosion was also quite  
12 variable, as high as 45%," and then two lines down it  
13 says, "the rate of dyspareunia has reached as high as  
14 60%. Here again grades of prosthetic retraction should  
15 be better defined."

16 So stopping there, is that information  
17 significant to you?

18 A. Yes, it is.

19 Q. Why is that?

20 A. Well, they're reviewing, you know, all the  
21 synthetic meshes around, saying there's a high rate of  
22 complication specifically when they're talking about  
23 the retraction.

24 Q. The next -- rephrase.



1           In the middle of the section of the summary it  
2   says, "Proposed to improve these phenomena, soft  
3   Prolene recently used by several authors does not  
4   appear to fulfill expectations."

5           Is that significant to you?

6           A.    Yes, it does.

7           Q.    Why is that?

8           A.    Because you have to look at, you know,  
9   that's why I mentioned the first part of this. They're  
10   talking about the historical things, the Marlexes and  
11   the Gortexes and the complication rates that were found  
12   with those; therefore, individuals said, let's use a  
13   different mesh. Let's use Prolene soft, okay. And  
14   then when they did that, and, again, this is the early  
15   days, these are the highest volume surgeons probably in  
16   the world at that time, and they said the Prolene soft  
17   did not meet -- reach the expectations they had hoped  
18   it would.

19          Q.    And when they talk about the authors, that  
20   includes Cosson, who developed the Prolift®?

21          A.    Yes, Cosson, among others, yes.

22          Q.    And soft Prolene, just to be clear, that's  
23   the mesh in the Prolift®?

24          A.    Correct.

1           Q.    Go down towards the bottom, the last  
2   paragraph, and it says in part, "The lack of data on  
3   the rate of complications and patient quality of life  
4   is unacceptable for this functional surgery. We still  
5   have reservations about widespread use of synthetic  
6   meshes."

7           Is that significant to you?

8           A.    Yes, very much so.

9           Q.    Why?

10          A.    Okay. Again, that's what I've been  
11   stating all along. This is a quality of life problem,  
12   okay. And these surgeons when they say functional,  
13   that means quality of life. And so they address what I  
14   already mentioned multiple times.

15          Q.    Let's go to the next exhibit PLT0696.

16          Doctor, Exhibit 0696, PLT0696, is an article  
17   titled "Evaluation and management of complications from  
18   synthetic mesh after pelvic reconstructive surgery: a  
19   multicenter study" by Dr. Abbott, et al.

20          Are you familiar with this article?

21          A.    Yes, I am, very much so.

22          Q.    And is this article medically reliable and  
23   authoritative in the field, in your opinion?

24          A.    It's a very good article, yes.

1 Q. Is this an article you've relied on in  
2 forming your opinions?

3 A. Yes, I have.

4 Q. What I would like to do first is turn to  
5 -- well, rephrase.

6 Very simply, what is this article about; what  
7 are they talking about?

8 MR. ISMAIL: Objection, hearsay, Exhibit  
9 696, standing objection.

10 MR. SLATER: Yep.

11 BY MR. SLATER:

12 Q. Let me ask the question again. What is  
13 this article about? Let's start in general, and then  
14 we'll go to specifics real quick.

15 A. The article, as it states, which is  
16 important, it's a multicenter study, so it's not just  
17 one institution. So it's experience of multiple  
18 different doctors, high volume, high profile, top notch  
19 surgeons, and they're evaluating the -- their  
20 complications that they have seen and referred in to  
21 their institution from meshes and then the outcome  
22 following these. So it's much more advanced study than  
23 the original Blandon one. Blandon one is early is.  
24 This is now late with multiple studies looking at this

1 problem.

2 Q. The concepts that we're going to talk  
3 about in this article, do they apply to the Prolift®,  
4 in your opinion?

5 A. Yes.

6 Q. Okay. Let's first turn to Page e3, and  
7 there's a Table 2.

8 Do you see that?

9 A. Yes, I do.

10 Q. And first at the top it says, there were  
11 347 patients?

12 A. Correct.

13 Q. And if you go down further it says,  
14 "smoking status." What is that telling us?

15 A. As it states, did the patient smoke, have  
16 they never smoked, past smoker or a lifetime nonsmoker.

17 Q. And what was the statistics on the 347  
18 patients?

19 A. Well, just reading it right off of there,  
20 never smoked was 61%, past smoker 21%, current smoker  
21 was 12.4%.

22 Q. And with regard to the concept of mesh  
23 erosion and complications that are discussed in this  
24 article, and we're going to get to them in a second,

1     what does this tell us about whether smoking, in your  
2     opinion, factors into that?

3             A.     Well, it's not just my opinion, but the  
4     opinion of these authors that smoking was not a factor  
5     because if you look at never smoked, 61%. If you add  
6     in there the previous but current nonsmokers, that  
7     equals a total of 82% nonsmokers. So 82% of the people  
8     weren't currently smoking and they had complications.

9             Q.     Let's go to page e5, if we could. And  
10    what I would like to do is draw your attention to the  
11    middle column, and the first full paragraph, about  
12    halfway down, and they're talking about the patients  
13    and some statistics on them, and it says, the most  
14    common complaints were mesh erosion (42.7%), pelvic  
15    pain (34.6%), and dyspareunia (30%), although most  
16    women (70.3%) had with greater than one distinct  
17    symptom or complaint.

18            What is significant, if anything, about that?

19            A.     It means you have, to be basic, a bunch of  
20    problems to fix. 70% were coming in with more than  
21    just one problem, and then it breaks it down what those  
22    various different problems are, but, I mean, it's not  
23    just one thing you have to try and fix.

24            Q.     Turn to the next page, the Comment

1 section, please, Page e6, and it says a little down  
2 from the beginning of the comment section,  
3 approximately one half of the women who sought  
4 treatment of a mesh-related complication at a tertiary  
5 referral center actually underwent their index  
6 procedure, or their first procedure, at another  
7 facility. This trend has been reported in other  
8 studies as well. This raises the potential concern  
9 that physicians who perform these mesh procedures may  
10 not be aware of the complications their patients  
11 experience and that these providers may be responsible  
12 for future mesh-related complications, with no  
13 awareness of the existing magnitude of the issue.

14 Is that significant to you?

15 A. Yes, it is.

16 Q. Why is that?

17 A. Well, for two different reasons. Number  
18 one, 50% of the procedures -- let's break it up into  
19 50/50. 50% of these procedures, these complications  
20 they're facing were done by high volume, high qualified  
21 surgeons, okay, so that raises a problem right there.

22 Number two, the other 50% were done by surgeons  
23 who are unaware that this complication is even  
24 existing, so it's multiple problems with that statement

1 right there.

2 Q. Let's look at the right-hand column on  
3 page e6, almost halfway down the page, there's a  
4 sentence that starts, "Furthermore, complications after  
5 TVM tend to be more severe, are more chronic in nature  
6 and can be more difficult to treat. For instance, mesh  
7 erosion, pelvic pain, dyspareunia, vaginal  
8 constriction, vaginal spotting and obstructive  
9 defecation were all significantly more common after  
10 index surgery with TVM than 1 with sling only."

11 Is that significant to you?

12 A. Oh, absolutely. They're describing here  
13 that this is a problem that we can't fix. In medical  
14 school, residency and advanced training, we are trained  
15 to fix problems. That's what doctors are supposed to  
16 do, and they're stating we can't fix it.

17 Q. Let's go down further on the third column  
18 on Page e6, almost to the bottom, about eight lines up,  
19 it says, "Most patients (60%) received 2 or more unique  
20 interventions; even then, there was no guarantee of  
21 symptom resolution."

22 What, if any, significance is that?

23 A. Okay. It's that there used to be this  
24 dogma of oh, treat a mesh exposure, that's it, it's

1     gone, no big deal.

2             What they're saying is it requires multiple --  
3     60% of their patients required two or more, and I think  
4     later on they say there's something like 12% required  
5     up to five or six, so it's a much larger number. I  
6     don't have any specifics right here. So but bottom  
7     line, it's a problem that continues to create more  
8     problems, and it can't just be resolved quickly.

9             Q.     The description of complications and the  
10    issues with treating the complications in this article,  
11    in your opinion, do these concepts apply to the  
12    Prolift®?

13            A.     Absolutely, yes.

14            Q.     Do you have an opinion as to whether or  
15    not this profile of complications is medically safe or  
16    unsafe for patients?

17                   MR. ISMAIL:   Objection, cumulative.

18    BY MR. SLATER:

19            Q.     What's your opinion?

20            A.     It's unsafe.

21            Q.     Let's go to the next exhibit, which is  
22    PLT1095, which I did give you before.

23                   MR. ISMAIL:   When we came in first thing  
24                   the morning?



1 MR. SLATER: Yes.

2 MR. ISMAIL: Thank you.

3 BY MR. SLATER:

4 Q. Doctor, Exhibit PLT1095 is an article  
5 titled "Surgical management of mesh-related  
6 complications after prior pelvic floor reconstructive  
7 surgery with mesh." There's a few authors,  
8 including -- is it Heesakkers?

9 A. John Heesakkers.

10 Q. Heesakkers and Mariëlla Withagen from  
11 2011.

12 Are you familiar with this article?

13 A. Yes, I am.

14 Q. Is this article medically reliable and  
15 authoritative in the field, in your opinion?

16 A. Yes, it is.

17 Q. Is this an article you relied on?

18 A. Yes.

19 Q. And do you know any of these authors?

20 A. I've heard Withagen speak. John  
21 Heesakkers, he is the chair of the European Urology  
22 Reconstructive Surgery, which I am a board member of,  
23 so I've talked to him, I've talked to him about mesh  
24 complications, so I know him personally.

1 Q. Let's turn -- this is a paper about the  
2 treatment of mesh complications, including Prolift®?

3 A. That's correct.

4 MR. ISMAIL: Objection to hearsay, Exhibit  
5 1095, also, on not disclosed previously as a  
6 reliance material for this witness.

7 Standing objection?

8 MR. SLATER: Standing objection.

9 MR. ISMAIL: Thank you.

10 BY MR. SLATER:

11 Q. Let's turn to the fourth page, Page 1398,  
12 and first I want to read something in the right-hand  
13 column. About halfway down the right-hand column it  
14 says, a distinct difference in frequency of  
15 mesh-related symptoms existed between the different  
16 types of mesh insertion procedure, especially in  
17 sacrocolpopexy compared to the other procedures. Pain  
18 and dyspareunia are mainly seen after mesh insertion  
19 and vaginal bleeding and discharge after  
20 sacrocolpopexy.

21 Is that significant to you?

22 A. Yes.

23 Q. Why is that?

24 A. Because then they're going back to this

1 issue of this being a quality of life problem and this  
2 patient having with the mesh kits, transvaginal mesh  
3 kits having the vaginal pain.

4 Q. I'm going to ask you to do something. Can  
5 you just grab the mesh from the anterior kit real  
6 quick.

7 With the abdominal sacrocolpopexy, is mesh  
8 used, where it's put in through the abdomen?

9 A. Yes, through the abdomen, which is  
10 different than through the vagina.

11 Q. And can you illustrate for the jury  
12 holding up the Prolift® how much mesh would be used in  
13 a abdominal sacrocolpopexy and give the jury some idea  
14 of the difference.

15 A. Well, you have to break it down so we can  
16 see it here. So this is the mesh for the anterior  
17 prolapse, anterior Prolift® and then the --

18 Q. Hold it up more.

19 A. The amount in contact with the vagina,  
20 we're not talking about the arms, just the vagina is  
21 going to be this part here, okay. And then you also  
22 have the arms, okay, which go through the muscles what  
23 I've already referred to.

24 Now, for the sacrocolpopexy, the robotic

1     sacrocolpopexy or the open procedure, the amount in  
2     contact with the vagina is going to be about that much,  
3     okay, maybe a little bit more, maybe a little bit less,  
4     and you'll be able to have it lie flat anteriorly, and  
5     there may be also a piece that size going posteriorly.  
6     In direct contact with the vagina is significantly  
7     less.

8             Q.     That size difference, what's the size of  
9     the amount of mesh, can you estimate the size of what's  
10    used with the abdominal procedure?

11            A.     Okay. It's going to be anteriorly, what's  
12    that, 2, maybe 3 centimeters, and also what I do is,  
13    and most people do, is you trim the top so it's a  
14    little more curved so it would actually be less than  
15    this. Let's just say 2 by 2 anteriorly, posteriorly  
16    maybe 2 by 3 centimeters, which is going to be  
17    significantly less, you can just visualize it,  
18    significantly less than the volume of mesh put in  
19    otherwise for the Prolift®.

20            Q.     So that's about an inch, 2 centimeters?

21            A.     2.54 centimeters in an inch.

22            Q.     So a little less.

23            A.     That's why I just said, just look at this.

24            Q.     Okay. Do you have an opinion as within --

1 as between abdominal sacrocolpopexy and the Prolift®  
2 procedure as to which one has a more or less acceptable  
3 safety and efficacy profile overall?

4 MR. ISMAIL: Objection, cumulative.

5 THE WITNESS: Yeah, the data will show the  
6 abdominal sacrocolpopexy, whether it be done  
7 robotically, laparoscopically or with an  
8 incision is a much safer procedure, with lower  
9 incidence of dyspareunia, chronic problems  
10 associated with Prolift®. So it's a -- you  
11 can't compare the two. They're apples and  
12 oranges as far as the procedure goes.

13 BY MR. SLATER:

14 Q. Let's turn now to Page 1402 of the article  
15 that we are discussing here. The Heesakkers-Withagen  
16 article and in the right-hand column, towards the top  
17 right, top paragraph, last sentence, it says, also, the  
18 urologist is always involved in the treatment of  
19 patients with (suspected) mesh complications affecting  
20 the bladder.

21 Is that significant to you?

22 A. Yes.

23 Q. Why is that?

24 A. Because what Withagen, who's a, you know,

1 highly trained, very good pelvic surgeon is what she's  
2 saying, and she gets another expert involved in the  
3 bladder, because these are so difficult to get out.

4 Q. Let's go down further in that column to  
5 the last -- the second to last -- really, the last full  
6 paragraph and about halfway down through that it says,  
7 "Of the patients included in this study, 20 underwent  
8 insertion of Prolift® at our hospital between halfway  
9 of 2005 and end of 2009. In this period, 180 Prolift®  
10 meshes were inserted. So, 20 out of 180, (11%)  
11 patients with Prolift® inserted at our center developed  
12 complications that required excision."

13 Is that significant to you?

14 A. Yes, it is, especially given the probably  
15 relatively short amount of follow-ups, that's a very  
16 high number.

17 Q. Having over 10% reoperations to remove  
18 mesh?

19 A. It's quite -- that's a very high number,  
20 yes.

21 Q. Finally, I want to go to the last page of  
22 the text. The Conclusion, the very bottom of the left  
23 column over to the top, I want to read something and  
24 ask you a question. So we're at the bottom of the left

1 column under the Conclusion, the last paragraph.

2 A. I'm there.

3 Q. It says, "The increasing number of  
4 inserted meshes for SUI and POP raises concerns. Mesh  
5 is successfully used for repair of prolapse, but when  
6 complications arise, they may be severe in nature and  
7 result in a decrease in quality of life. New meshes  
8 are introduced into clinical practice, despite the lack  
9 of proper studies showing their safety and  
10 effectiveness. Moreover, the use of easy-to-do mesh  
11 kits lowers the threshold for inexperienced surgeons to  
12 start operating with meshes. This can only lead to  
13 more complications, which is harmful for the patients."

14 Is that significant to you?

15 A. Very much so, yes.

16 Q. Why is that?

17 A. Well, you go point by point through here  
18 is -- in the first line, mesh is successfully used to  
19 repair prolapse. You know, I agree with that, that  
20 they can repair prolapses. Now we had a high failure  
21 rate, it's 20% or so, but that's not the issue. It's  
22 that these complications are the problem. That's the  
23 life-changing aspect of it and that they're introduced  
24 without any studies, okay. There were no human studies

1 on Prolift® prior to release, okay. To my opinion that  
2 is unethical and unacceptable.

3 And then, number three, this gets into more of  
4 a discussion, these easy kits allow inexperienced  
5 to start -- inexperienced surgeon, to allow them to  
6 operate, that's beyond the scope of this here. But it  
7 raises the ability for people who are not advanced  
8 surgeons of doing these things. Again, that's, to a  
9 certain degree, a different issue here.

10 MR. ISMAIL: In addition to hearsay, which  
11 has been preserved, move to strike as  
12 nonresponsive and not proper grounds for expert  
13 testimony.

14 BY MR. SLATER:

15 Q. Let's go to the next exhibit.

16 Doctor, I've handed you what we've marked as  
17 Exhibit -- actually, what number is on that?

18 A. P2731.

19 Q. Is it P or PLT?

20 A. P.

21 Q. Just P, okay. Okay. Let me start over.

22 Doctor, I've handed you Exhibit P2731, and this  
23 is a page from the New England Journal of Medicine?

24 A. That is correct.



1 Q. And in the bottom right-hand column  
2 there's a set of corrections.

3 Do you see that?

4 A. Yes, I do.

5 Q. And the bottom one says that there was a  
6 correction to an article titled "Anterior Colporrhaphy  
7 versus Transvaginal Mesh for Pelvic Organ Prolapse,"  
8 published in the New England Journal of Medicine,  
9 May 12, 2011.

10 And are you familiar with that article?

11 MR. ISMAIL: Objection, hearsay.

12 THE WITNESS: Yes, I am, the Altman study,  
13 I'm familiar.

14 BY MR. SLATER:

15 Q. And they talk about a correction that was  
16 made to some language in the Altman study of the  
17 Prolift®?

18 A. That is correct.

19 MR. ISMAIL: Objection, hearsay.

20 Standing objection 2731.

21 BY MR. SLATER:

22 Q. If somebody in this courtroom were to have  
23 relied on the Altman study to say that that is proof of  
24 the safety or efficacy or that the Prolift® is a

1     suitable device or system, what would be your response  
2     to that based on the correction and the information you  
3     have available to you from the depositions of the  
4     editors of the New England Journal of Medicine and the  
5     internal documents you've seen from the company?

6                     MR. ISMAIL: Objection, hearsay, 403.

7     BY MR. SLATER:

8                     Q.     You can answer.

9                     A.     Based upon what I have read, as you  
10    mentioned, the depositions from the journal -- New  
11    England Journal of Medicine editors, what I've read of  
12    internal documentation, of correspondence going back  
13    and forth between the author and key people, three or  
14    four within Ethicon, that the author originally stated  
15    that this data was not -- had no industry involvement.  
16    And then we come to find out that roughly, what, 100 or  
17    so changes were made by Ethicon on this document.

18                    Subsequently, there's no disclosure of bias,  
19    which is the reason why rules exist is to declare if  
20    there's a potential bias. So that Altman study, along  
21    with other errors that were pointed out on POP-Q scores  
22    makes that study unreliable and false.

23                    Q.     When you talk about errors with POP-Q  
24    scores, what are you talking about, and why is that

1 significant in assessing the validity of the Altman  
2 study?

3 MR. ISMAIL: Objection, 403, hearsay.

4 THE WITNESS: POP-Q is a grading system,  
5 POP-Q, pelvic organ prolapse quantification of  
6 the prolapse, okay. It's basic numbers and  
7 certain POP-Q scores, we should abbreviate  
8 POP-Q, because it's just easier. It's a very  
9 logical system, and so in my review of these  
10 internal documents, e-mails back and forth and  
11 depositions, we find out that those POP-Q  
12 scores are not possible, not physically  
13 possible, so, therefore, that data is false.  
14 That's why I have been privy to information the  
15 average doctor on the street has not been. So,  
16 again that's why it's a major because it  
17 undermines the very core and validity of that  
18 information.

19 MR. ISMAIL: Objection, move to strike,  
20 nonresponsive.

21 BY MR. SLATER:

22 Q. Let's go to the next PowerPoint slide.

23 Doctor, I want to ask you about some  
24 characteristics of the Prolift® and ask you a question

1 about them, okay?

2 A. Okay.

3 Q. First of all, did you compile a list of  
4 what you believe to be medically unsafe Prolift®  
5 characteristics?

6 A. Yes, in an abbreviated form listed here,  
7 yes.

8 Q. The first one, "tension is unavoidable/no  
9 'tension free'"

10 MR. ISMAIL: Object to the -- sorry.

11 BY MR. SLATER:

12 Q. You've talked about these things, some of  
13 them at length, but I just want you to briefly just  
14 tell us why you include that in the list?

15 MR. ISMAIL: Object to the slide as  
16 argumentative, object to the testimony as  
17 cumulative.

18 THE WITNESS: Tension free is not  
19 physically possible within the female pelvis.  
20 So that's why it's tension free is -- tension  
21 is going to happen, which then goes down to one  
22 of the root sources of problems, where you get  
23 tension, you get the pore size collapse, then  
24 you cause that inflammation, foreign body

1 reaction, scarring and pain.

2 BY MR. SLATER:

3 Q. Number 2, mesh does not lay flat in an  
4 unstretched condition.

5 Why do you say that?

6 MR. ISMAIL: Objection, cumulative.

7 THE WITNESS: As I stated earlier, you  
8 can't get that mesh to lie flat. If it doesn't  
9 lie flat, it bunches, it curls, ropes and then  
10 that causes, again, that cascade of the  
11 problem, pore size decrease, foreign body  
12 reaction, inflammation, pain.

13 BY MR. SLATER:

14 Q. With regard to the arms, roping, curling  
15 and banding, location in obturator space and deep  
16 pelvis, why do you include that?

17 MR. ISMAIL: Objection, cumulative.

18 THE WITNESS: The roping, curling and  
19 banding, we showed multiple times here, that's  
20 going to cause that -- those arms to roll up,  
21 scar. They band, you can feel them on physical  
22 exam. Going through the obturator foramen  
23 space and deep pelvis, the significance of that  
24 is it's going to anchor it in and those

1           muscles, those multiple muscles that have been  
2           pierced will then contract with pain -- excuse  
3           me -- with activity causing pain.

4   BY MR. SLATER:

5           Q.   Mesh does not incorporate safely in the  
6   pelvis.

7           What does that mean?

8           MR. ISMAIL:  Objection, cumulative.

9           THE WITNESS:  That's what we've been  
10          stating multiple times.  This mesh is not a  
11          safe product to be placed in the female pelvis  
12          transvaginally.

13  BY MR. SLATER:

14          Q.   Difficult/impossible to safely and  
15          effectively remove the mesh.

16          Why do you say that?

17          MR. ISMAIL:  Objection, cumulative.

18          THE WITNESS:  Because the product when put  
19          in for a quality of life issue, it is  
20          impossible to get that mesh out completely.  
21          You can leave behind or do severe damage to the  
22          pelvic structures in trying to take it out.

23  BY MR. SLATER:

24          Q.   Do you hold those opinions to a reasonable

1 degree of medical certainty?

2 A. Yes, those are based upon my personal  
3 experience, review of the literature, internal  
4 documentations, everything.

5 Q. Based upon the list of medically unsafe  
6 Prolift® characteristics that you have compiled, do you  
7 have an opinion as to whether or not the Prolift®  
8 system is a defective -- defectively designed system  
9 and procedure for the treatment of pelvic organ  
10 prolapse?

11 MR. ISMAIL: Objection, cumulative, lack  
12 of foundation, lack of qualifications.

13 THE WITNESS: As I've mentioned, based  
14 upon my experience in taking care of these  
15 complications, my experience performing the  
16 traditional repairs without mesh, that this was  
17 an unsafe, poorly designed product that has no  
18 role being placed in the female pelvis.

19 BY MR. SLATER:

20 Q. Let's go to the next slide.

21 Doctor, did you compile a list of injuries  
22 caused by medically unsafe Prolift® characteristics,  
23 meaning what the consequences are of the list of  
24 characteristics you listed on the prior slide?

1 MR. ISMAIL: Objection. Sorry.

2 Objection, the slide is argumentative, also 403  
3 as being -- many of these being irrelevant to  
4 the plaintiff at issue.

5 MR. SLATER: I'm going to ask the question  
6 differently.

7 BY MR. SLATER:

8 Q. Doctor, I'd like to talk about a list of  
9 injuries caused by medically unsafe Prolift®  
10 characteristics, a list that we have here to talk  
11 through, okay?

12 A. Okay.

13 Q. Is this list applicable to the Prolift® in  
14 those issues that you just went through on the prior  
15 slide?

16 MR. ISMAIL: Same objection.

17 THE WITNESS: Yes.

18 BY MR. SLATER:

19 Q. Doctor, I'm going to walk through these  
20 one at a time.

21 Chronic, severe inflammation, why is that, in  
22 your opinion, a result of a medically unsafe  
23 characteristic of the Prolift®?

24 MR. ISMAIL: Objection, 403.



1 THE WITNESS: Because you're treating a  
2 quality of life problem, prolapse, and if you  
3 place a device in there that has chronic,  
4 severe, permanent and progressive inflammation,  
5 it's unacceptable to trade a quality of life  
6 problem with a viable, acceptable alternative  
7 and trade it for a chronic, permanent problem.

8 BY MR. SLATER:

9 Q. Contraction of the mesh, and then you have  
10 the term excessive. Tell us what that means and why  
11 that is, in your opinion, applicable?

12 MR. ISMAIL: Objection, 403, cumulative.

13 THE WITNESS: The key with that is, number  
14 one, contraction, so the mesh shrinks down as a  
15 result of the scarring and inflammation, but  
16 then excessive, so it's pulling on the muscles,  
17 causing the pain, causing banding, rolling and  
18 subsequently causing mesh exposure, so it  
19 causes multiple different problems.

20 BY MR. SLATER:

21 Q. Scar plating and fibrotic bridging,  
22 explain that, why that is a result of the Prolift®?

23 MR. ISMAIL: Objection, 403, cumulative.

24 BY MR. SLATER:

1 Q. And what you've called medically unsafe  
2 Prolift® characteristics?

3 MR. ISMAIL: Cumulative.

4 BY MR. SLATER:

5 Q. Scar plating, fibrotic bridging, Number 3.

6 A. Thank you. Again, this goes back to the  
7 fundamental problem with the mesh of causing that  
8 plating. It doesn't cause tissue integration, where it  
9 goes through those pores. It causes that plating,  
10 which then causes the mesh to contract; bridging, which  
11 causes pain for both the partner -- excuse me -- for  
12 the patient in sexual activity with the partner also,  
13 along with other as far as just ambulation.

14 Q. Extrusion/exposure/erosion of mesh -  
15 complex/recurrent. What are you talking about there,  
16 and why is that an injury caused by a medically unsafe  
17 Prolift® characteristic?

18 MR. ISMAIL: Objection, 403, cumulative.

19 THE WITNESS: Due to the design of this  
20 product, what I see in my daily practice,  
21 because those pores constrict, because you get  
22 this fibrosis or persistent infection, you can  
23 get extrusion of the mesh, exposure, and the  
24 key here is complex and recurrent, meaning it's

1 not just one quick little procedure and it's  
2 done. As that Abbott study showed it comes  
3 back multiple times.

4 MR. ISMAIL: Objection, move to strike,  
5 hearsay.

6 BY MR. SLATER:

7 Q. Vaginal pelvic pain, which can be chronic.  
8 Why is that the result of a medically unsafe Prolift®  
9 characteristic?

10 MR. ISMAIL: Objection, 403, cumulative.

11 THE WITNESS: This is one of the biggest  
12 issues which I see in my clinic on a weekly  
13 basis is that we now have a quality of life  
14 problem of this pelvic organ prolapse. Woman  
15 has fullness, pressure, and then now we've  
16 traded it for a chronic, progressive,  
17 permanent, unfixable problem, okay. So the  
18 women's quality of life, these are the patients  
19 that I have in my clinic, they and their  
20 spouse, they're crying because they are ruined  
21 because of a quality of life problem when there  
22 was a viable other option available.

23 MR. ISMAIL: Move to strike,  
24 nonresponsive.

1 BY MR. SLATER:

2 Q. Dyspareunia, which can be chronic, why is  
3 that a result of a medically unsafe Prolift®  
4 characteristic?

5 MR. ISMAIL: Objection, cumulative.

6 THE WITNESS: That's just the same thing  
7 as what I just mentioned as far as with the  
8 vaginal pain, pelvic pain. Quality of life  
9 problem for permanent progressive problem is  
10 not fixable.

11 BY MR. SLATER:

12 Q. Pelvic floor myalgia, otherwise known as  
13 muscle spasms, which can be chronic, why does that  
14 result from medically unsafe Prolift® characteristics,  
15 in your opinion?

16 MR. ISMAIL: Objection, 403, cumulative.

17 THE WITNESS: This is due to those mesh  
18 arms going through all those muscles that I  
19 mentioned. When they pull, they tug, the  
20 pelvic musculature becomes irritated and  
21 painful, and so it's directly due to the  
22 presence of that foreign body and the arms in  
23 the product.

24 BY MR. SLATER:

1           Q.     Urinary dysfunction, which can be chronic,  
2     why is that a result of medically unsafe Prolift®  
3     characteristics, in your opinion?

4           MR. ISMAIL:   Objection, 403, cumulative.

5           THE WITNESS:   Okay.   Due to the placement  
6     where this is placed, in the vesicovaginal  
7     space, in between the bladder and the vagina,  
8     where all the nerves for bladder function come  
9     in like this, you now have created that foreign  
10    body, which is going to cause contraction,  
11    erosion, inflammation, and it's going to  
12    affecting those nerves causing permanent  
13    bladder dysfunction, which you can't fix.

14   BY MR. SLATER:

15           Q.     Mesh removal operations, why do you  
16     include that as injuries caused by medically unsafe  
17     Prolift® characteristics?

18           MR. ISMAIL:   Objection, 403, cumulative.

19           THE WITNESS:   Every surgery has risks to  
20     it, especially as the individual becomes older,  
21     there's data out there showing mentation  
22     issues, et cetera.   So if the patient undergoes  
23     multiple surgeries to try and fix this, besides  
24     just the expense of it, the wear and tear on

1 the human body, it's not just a one and done,  
2 easy fix, office procedure.

3 BY MR. SLATER:

4 Q. Doctor, you said earlier, and I'll just  
5 confirm it, you said you're familiar with the IFU for  
6 the Prolift®?

7 A. Yes, I am.

8 Q. This profile of injuries, complications  
9 that can be caused by the Prolift®, in your opinion, is  
10 that adequately warned of in any IFU for the Prolift®  
11 that you've ever seen?

12 MR. ISMAIL: Objection, lack of  
13 foundation, lack of qualifications.

14 THE WITNESS: No.

15 BY MR. SLATER:

16 Q. Is the medical information that is set  
17 forth in this list that you have compiled found in the  
18 Prolift® IFU, in your opinion?

19 MR. ISMAIL: Same objections.

20 THE WITNESS: No.

21 BY MR. SLATER:

22 Q. Is it important to not only warn of  
23 specific individual risks but also of the entire full  
24 spectrum of the risks at the same time?

1 A. Yes.

2 Q. Why does that matter?

3 A. The IFU needs to warn about all the known  
4 complications, their severity, their frequency, so you  
5 got to -- and the ability to change it. So you've got  
6 to warn for all of those potential factors, which were  
7 all known.

8 MR. ISMAIL: Objection, move to strike  
9 under 705. Sorry.

10 BY MR. SLATER:

11 Q. Let me ask you this: Is it important for  
12 the entire risk profile and the most severe  
13 complications to be fully disclosed to the doctor?

14 A. Yes.

15 Q. Why is that?

16 MR. ISMAIL: Same objection.

17 THE WITNESS: The doctor, as a surgeon  
18 myself, I need to know so I can relay  
19 accurately to the patient, a human being that's  
20 sitting in my office, I have to be able to tell  
21 them, here's what we can expect, I have to be  
22 told all known complications, severity and  
23 their nature, what is known, so I can  
24 accurately consent my patient.

1 BY MR. SLATER:

2 Q. Does that also enter into the risk-benefit  
3 analysis and what recommendations are made and how  
4 they're made?

5 A. Absolutely.

6 Q. Let's go to the next slide, "Treatment of  
7 Prolift® Complications."

8 Doctor, this list of treatment of Prolift®  
9 complications, I'll let you just walk through it and  
10 just quickly tell us, first of all, are these  
11 treatments that are known to be, in your opinion, to be  
12 necessary to treat various complications from a  
13 Prolift®?

14 MR. ISMAIL: Objection, cumulative and  
15 403.

16 THE WITNESS: Many times, yes.

17 BY MR. SLATER:

18 Q. Okay. Just go through them one at a time.  
19 Tell us what you're specifically talking about and just  
20 tell us so we understand what they are.

21 A. Sure. I did not list the --

22 MR. ISMAIL: Objection. Sorry, doctor.

23 I'll let you restart, but objection, cumulative  
24 and 403.



1                   THE WITNESS: I did not list these in  
2                   level of complexity, which I probably should  
3                   have, but starting off with mesh removal  
4                   operation, this is to remove the mesh, that can  
5                   be removal of an exposure, it's outpatient type  
6                   procedure versus the complete removal of the  
7                   mesh, which is a major transabdominal belly  
8                   procedure, highly complicated thing. So that  
9                   falls in the next point of just surgical care.  
10                  These are complicated procedures requiring  
11                  multiple office visits, multiple follow-up,  
12                  multiple effect upon the individual's usual  
13                  lifestyle, okay.

14                  Pain management/injections, another option  
15                  for treating pelvic pain. This is the majority  
16                  of what I see. Unfortunately, I have yet to  
17                  have, in my experience now, since meshes have  
18                  come out, so now it's, what, ten years now, I  
19                  have yet to have a successful pain management  
20                  patient with meshes, I can't fix them. I have  
21                  a physical therapy team. I have a nurse who  
22                  works in biofeedback. I have an anesthesia  
23                  pain clinic, can't fix them. So it's a  
24                  permanent problem.

1 Pelvic floor physical therapy, that's what  
2 I just mentioned, biofeedback, again, an  
3 option. I have had zero success.

4 Spinal --

5 Q. Let me just stop you there. Were you  
6 talking about success in terms of completely treating  
7 the condition and making the person completely better?

8 A. No. I'm talking about a significant  
9 reduction in their symptoms. I'm not -- I do not try  
10 to make -- let me back up.

11 I would love to be able to make someone pain  
12 free. I'm realistic, I can't. I am happy if I can get  
13 a significant reduction in their pain. I can't even  
14 get that, and I've got arguably some of the best people  
15 around to help me out, and I can't do it. I wish I  
16 could.

17 Q. Let's go on, spinal stimulator.

18 MR. ISMAIL: Objection, 403, cumulative.

19 THE WITNESS: The spinal stimulator  
20 evolved with our pain clinic. It's just  
21 another way of injecting pain medication to the  
22 spine or locally.

23 Catheterization is dealing for bladder  
24 dysfunction that occurs afterwards, where the

1           woman is in retention and can't urinate because  
2           of contraction.

3                   Medication is again going down the lines  
4           of bladder spasm medication or pain medication,  
5           which I allow my pain clinic colleagues to deal  
6           with that.

7   BY MR. SLATER:

8           Q.    Okay.  Let's go to the next PowerPoint  
9   slide.  Doctor, I want to ask you about a statement  
10  made by David Robinson in his deposition of March 13,  
11  2012, Page 52, Line 11 to 15 and ask you a question  
12  about it.

13                  First of all, you read that deposition; you  
14  know this testimony?

15           A.    Yes, I did.

16           Q.    >Data should establish that the benefits  
17  far outweigh the risks before the product is sold for  
18  widespread use."

19                  Did Ethicon ever establish data that would  
20  satisfy that criteria?

21                   MR. ISMAIL:  Objection to the use of the  
22           slide as argumentative, and testimony is  
23           cumulative, lack of foundation.

24                   THE WITNESS:  No.

1 BY MR. SLATER:

2 Q. Do you have an opinion to a reasonable  
3 degree of medical certainty as to whether or not the  
4 overall risk-benefit profile for the Prolift® was  
5 medically acceptable?

6 MR. ISMAIL: Objection, cumulative.

7 THE WITNESS: It was not medically  
8 acceptable.

9 BY MR. SLATER:

10 Q. And is that for the reasons you've stated  
11 throughout your testimony?

12 MR. ISMAIL: Same objection.

13 THE WITNESS: Yes.

14 BY MR. SLATER:

15 Q. Let's go to the next PowerPoint slide. I  
16 want to ask you about some testimony that Ethicon  
17 medical affairs directors gave regarding the standards  
18 they described for what the warnings of risks needed to  
19 communicate.

20 Are you familiar with what that testimony was?

21 A. Yes, I've read all those depositions.

22 Q. And is that testimony something that  
23 you've relied on in forming your opinions?

24 A. Yes.

1 Q. And do you agree with the descriptions of  
2 the criteria for what warnings needed to communicate  
3 regarding risks as testified to by the medical affairs  
4 directors; do you agree with that testimony?

5 MR. ISMAIL: Objection to the slide as 403  
6 and argumentative and to the testimony as 403,  
7 argumentative and without qualification.

8 THE WITNESS: Yes, I agree to each of  
9 those five points I pointed out.

10 BY MR. SLATER:

11 Q. And just to be clear, Doctor, to meet any  
12 objection, in your practice, you have utilized and not  
13 only utilized but taught residents the use of the IFU,  
14 including risk information?

15 A. Oh, absolutely, yes.

16 Q. And, in your experience, is it necessary  
17 for you to understand how to read an IFU and literature  
18 from a manufacturer to determine how to use that risk  
19 information in treating patients?

20 A. Absolutely. I have to trust what I read  
21 on the IFU, so that's why I relay on to the patients  
22 and relay on to my residents during education.

23 Q. Let's go to the next exhibit, Exhibit  
24 P1005.

1 Doctor, let me start over. Get a drink of  
2 water.

3 Doctor, looking at Exhibit P1005, this is an  
4 IFU that Ethicon has advised us was in effect from 2007  
5 until, I believe, September 2009.

6 Are you familiar with this IFU?

7 A. Yes, I am.

8 Q. And you've talked about it before. You're  
9 familiar with the document and the various bits of  
10 information in there?

11 A. Yes.

12 Q. I want to just ask you to just run through  
13 a few things and ask you brief questions about them.  
14 Let's go to the second page. There is a heading  
15 halfway down just below the table that says "Gynecare  
16 Gynemesh® PS," and that's the name of the mesh material  
17 in the Prolift®?

18 A. That is correct.

19 Q. The last sentence of that section says,  
20 "The bi-directional elastic property allows adaptation  
21 to various stresses encountered in the body."

22 Are you familiar with that statement in this  
23 IFU?

24 A. Yes.

1 Q. Have you in all the materials you've  
2 reviewed seen whether Ethicon had any data to support  
3 making that claim in the IFU?

4 A. They had none.

5 Q. Do you have an opinion as to whether or  
6 not it was appropriate or inappropriate for Ethicon to  
7 make that statement in the IFU?

8 MR. ISMAIL: Objection, improper expert  
9 testimony.

10 THE WITNESS: It would be inappropriate  
11 and misleading to the surgeon.

12 MR. ISMAIL: Move to strike,  
13 nonresponsive.

14 BY MR. SLATER:

15 Q. Based on your knowledge and experience and  
16 familiarity with the literature and the use of IFUs, do  
17 you have an opinion as to whether surgeons expect that  
18 the information in an IFU is accurate?

19 MR. ISMAIL: Objection, improper expert  
20 testimony.

21 THE WITNESS: You expect and I used to  
22 expect it to be honest and truthful.

23 BY MR. SLATER:

24 Q. What do you mean by used to?

1 MR. ISMAIL: Objection, 403, improper  
2 testimony for an expert.

3 THE WITNESS: In my daily practice as a  
4 surgeon, and I had reviewed these, I had  
5 expected in the past to have it be an honest  
6 representation of what was known, so that I  
7 could relay honestly to my patients, people  
8 that I care for and am trained to care for, and  
9 now I do not believe that is true anymore.

10 MR. ISMAIL: Objection, move to strike.

11 BY MR. SLATER:

12 Q. Let's go to Page 5 of the IFU, and there's  
13 a section under Performance, and it indicates at the  
14 very bottom Page 5. Let's start over.

15 Let's go to Page 5 of the IFU, Doctor. There's  
16 a little number 5 in the bottom right.

17 You see it?

18 A. Yes.

19 Q. And at the bottom of the page there is a  
20 section that says Performance.

21 A. Yes.

22 Q. And in that section regarding the mesh  
23 material and the Prolift® it says that it "elicits a  
24 minimum to slight inflammatory reaction, which is



1     transient."    I want to stop there.

2                   Do you have an opinion as to whether that is an  
3     accurate statement or not?

4                   A.    I have an opinion, yes.

5                   Q.    And what is your opinion?

6                   A.    It is wrong.

7                   Q.    Why do you say that?

8                   A.    Because the foreign body reaction as  
9     documented in the literature what I've seen in my  
10    personal experience and the internal documentation is  
11    not minimum to slight, and it is permanent and  
12    progressive.

13                   MR. ISMAIL:  Objection, move to strike,  
14                   hearsay.

15   BY MR. SLATER:

16                   Q.    It indicates in the Performance section  
17    that there will be "a minimum to slight inflammatory  
18    reaction, which is transient, and is followed by the  
19    deposition of a thin, fibrous layer of tissue which can  
20    grow through the interstices of the mesh."

21                   Do you have an opinion as to whether or not  
22    that is a fully accurate and fully fair disclosure of  
23    what occurs?

24                   A.    I have an opinion, yes.

1 Q. What's your opinion?

2 A. That it is incorrect.

3 Q. Why?

4 A. Based upon my experience, my physical exam  
5 of hundreds of women, it is not a thin, fibrous layer.  
6 It's thick, it's bunched up, it's firm.

7 MR. ISMAIL: Move to strike under 403.

8 BY MR. SLATER:

9 Q. In the Performance section, about halfway  
10 down through that it says, "the mesh remains soft and  
11 pliable."

12 Do you see that statement? Do you have an  
13 opinion as to whether that is accurate?

14 A. It is false.

15 Q. Why do you say that?

16 A. That's based upon my own physical exams on  
17 patients, review of the literature, review of internal  
18 documents. It gets firm and fixed, rigid.

19 MR. ISMAIL: Objection, move to strike as  
20 hearsay, 403.

21 BY MR. SLATER:

22 Q. Did you see testimony of Axel Arnaud, the  
23 medical affairs director in France with regard to  
24 whether the mesh stays soft?

1           A.    I saw his and other people's depositions,  
2    yes.

3           Q.    And what did he say about whether it stays  
4    soft over time?

5           A.    It does not.

6           Q.    Now, there are statements in the IFU  
7    regarding the indications or contraindications, and I  
8    want to ask you a question -- and we'll have to go back  
9    to an exhibit we used previously. I want to ask you a  
10   question about who the appropriate patients are for the  
11   Prolift® as stated in the IFU.

12           So, first of all, PLT0062 was one of the first  
13   exhibits we used. If you just put that aside, we're  
14   going to need that -- let me start over.

15           Doctor, on Page 2 of the IFU it says  
16   Indications right towards the top and it says it's  
17   indicated for tissue reinforcement and long-lasting  
18   stabilization of the fascial structures of the pelvic  
19   floor, et cetera.

20           You see that?

21           A.    Yes, I do.

22           Q.    And then on Page 6 there are  
23   contraindications listed at the very top.

24           You see that, the very top of the page?

1 A. Yep.

2 Q. Is there anywhere in this IFU where it's  
3 indicated that the Prolift® is intended only for  
4 advanced prolapse Stage III or IV?

5 MR. ISMAIL: Objection, lack of relevance,  
6 403.

7 THE WITNESS: It does not state anything  
8 in regard to indication of a prolapse stage.

9 BY MR. SLATER:

10 Q. And let's go now in Exhibit PLT0062 to  
11 Page 587, the second to last page of that exhibit, and  
12 this is the article by the TVM group, the doctors who  
13 developed the Prolift®?

14 A. Yes, by the inventors of the product, yes.

15 Q. And right in the middle of the conclusion  
16 it says, "this technique should be reserved to the  
17 management of grade 3 and 4 prolapse, possibly as  
18 first-line treatment."

19 Do you see that?

20 MR. ISMAIL: Objection, hearsay, lack of  
21 relevance, 403.

22 THE WITNESS: Yes, I do.

23 BY MR. SLATER:

24 Q. Is that of significance to you?

1 MR. ISMAIL: Same objections.

2 THE WITNESS: Yes.

3 BY MR. SLATER:

4 Q. Why?

5 MR. ISMAIL: Same objection.

6 THE WITNESS: The surgeons who at this  
7 point in time have the largest experience about  
8 this product and what it'd be indicated for and  
9 including the complications felt that it should  
10 be reserved only for the more severe prolapses.

11 BY MR. SLATER:

12 Q. And when they say possibly as first-line  
13 treatment, what does that mean?

14 MR. ISMAIL: Same objections.

15 THE WITNESS: It means that for an  
16 individual who comes in who has never had a  
17 previous prolapse repair, that may be in their  
18 opinion for the higher grade prolapses, it can  
19 be used as first-line treatment.

20 BY MR. SLATER:

21 Q. And is that significant to you?

22 MR. ISMAIL: Same objections.

23 THE WITNESS: Very much so, as a surgeon.

24 BY MR. SLATER:

1 Q. With regard to the information in the IFU,  
2 is that significant to you?

3 MR. ISMAIL: Same objections.

4 THE WITNESS: Well, absolutely. As a  
5 surgeon who when papers originally come out,  
6 you look to the original authors to say, help  
7 me, guide me through this and when this is  
8 indicated. So, yeah, it's a very important  
9 statement for me.

10 BY MR. SLATER:

11 Q. Do you have an opinion as to whether that  
12 information should have been included in the Prolift®  
13 IFU?

14 A. The surgeons --

15 MR. ISMAIL: Objection.

16 BY MR. SLATER:

17 Q. Do you have an opinion on that?

18 A. Yes.

19 Q. What is your opinion as to whether that  
20 information should have been provided?

21 MR. ISMAIL: Objection, lack of relevance,  
22 403.

23 THE WITNESS: It should have been.

24 BY MR. SLATER:

1 Q. Why is that?

2 MR. ISMAIL: Same objections.

3 THE WITNESS: Because these surgeons are  
4 the authority at this point in time. They have  
5 the most experience. They know the good and  
6 the bad of this product, and so they're saying  
7 be careful, only put this in high grade  
8 prolapses, maybe as a first line treatment.  
9 They're not recommending that. So that's the  
10 kind of information I want relayed on by an  
11 industry.

12 MR. ISMAIL: Objection, hearsay, move to  
13 strike.

14 BY MR. SLATER:

15 Q. And when you give that opinion, you're not  
16 just talking about for yourself, you're giving that  
17 opinion as to what surgeons, in general, would need?

18 MR. ISMAIL: Same objections.

19 THE WITNESS: Absolutely, I'm an educator.  
20 I'm teaching the next generation of surgeons.  
21 I'm also involved in SUFU, the Society of  
22 Urodynamics and Female Urology, where we're  
23 trying to teach all those out in private  
24 practice. So, yeah, we have to rely on these

1 guidelines to help us point at the best way to  
2 treat patients.

3 BY MR. SLATER:

4 Q. Okay. We'll go to next exhibit now,  
5 PLT0516. This is an article by Dr. Withagen,  
6 "Trocarguided Mesh Compared With Conventional Vaginal  
7 Repair in Recurrent Prolapse, A Randomized Controlled  
8 Trial."

9 Are you familiar with this article?

10 A. Yes. And this should be pointed out that  
11 this was first study where she's doing this work and  
12 then we had a follow-up study that we've already  
13 reviewed with the complications as a result of this  
14 procedure.

15 Q. All right. Let me ask you the question  
16 again.

17 Doctor, are you familiar with this article?

18 A. Yes, I am.

19 Q. Is this article medically reliable and  
20 authoritative?

21 A. Yes, it is.

22 Q. Is this something you've relied on in  
23 forming your opinions?

24 A. Definitely.



1 Q. Right on the front it talks about the fact  
2 that we with these Prolift® patients, the bottom of the  
3 results section, "Mesh exposure was detected in 14 of  
4 83 patients (16.9%)."

5 Is that significant to you?

6 MR. ISMAIL: Objection, hearsay. Standing  
7 objection, please.

8 MR. SLATER: Yes.

9 THE WITNESS: Yes.

10 BY MR. SLATER:

11 Q. Why?

12 A. Because in this high volume, talented  
13 individual or these surgeons, they had essentially 17%,  
14 to be specific, 16.9% risk of mesh exposure at only 12  
15 months. Remember, this is a device that's going to be  
16 in a woman forever, and at one year already 16.9% have  
17 exposure.

18 Q. Do you have an opinion as to whether that  
19 level of a mesh exposure rate is acceptable or  
20 unacceptable from a medical standpoint?

21 A. It is unacceptable, yeah, absolutely it's  
22 unacceptable.

23 Q. Let's go to the last page of the article,  
24 Page 250, the last paragraph. And the second sentence

1 of the last paragraph says, "Because the long-term  
2 effects and safety of mesh-reinforced repairs are not  
3 yet fully known, surgeons may consider these procedures  
4 primarily for recurrent vaginal prolapse after  
5 counseling patients on the risks and benefits."

6 Is that statement significant to you?

7 A. Yes.

8 Q. Why?

9 A. Once again, in this high volume surgeon,  
10 they're saying that even as of 2011, we still don't  
11 know the true complications that can occur with this,  
12 and so it only should be reserved for individuals with  
13 a recurrent prolapse. They have already had a surgery  
14 and it's failed and it needs surgery again. So it's  
15 reserving it for a very small subgroup.

16 Q. And, in your opinion, do you think --  
17 rephrase.

18 Do you have an opinion as to whether the IFU  
19 should have limited the scope of patients who would be  
20 acceptable, candidates as listed in that article by  
21 Withagen?

22 MR. ISMAIL: Objection, sorry. In  
23 addition to hearsay, cumulative, 403.

24 THE WITNESS: Absolutely, I have an

1           opinion about it.

2       BY MR. SLATER:

3           Q.     What is that?

4           MR. ISMAIL:   Same objection.

5           THE WITNESS:   It should have been listed.

6       BY MR. SLATER:

7           Q.     Let's go to the next exhibit.

8           Doctor, looking at Exhibit P980, it's some  
9     e-mails, January of 2005, about two months before the  
10    Prolift® went on the market.

11          Are you familiar with this e-mail chain?

12          A.     Yes, I've seen it.

13          Q.     What I'd like to do is turn to the second  
14    page, e-mail from Axel Arnaud, the medical affairs  
15    director at Ethicon in France, and he's proposing a  
16    warning.

17          And have you seen this e-mail and this proposed  
18    warning?

19          A.     Yes, I have.

20          Q.     And just for the record, I'll read it and  
21    then I have to ask you a question.

22          "Warning: Early clinical experience has shown  
23    that the use of mesh through a vaginal approach can  
24    occasionally/uncommonly lead to complications such as

1 vaginal erosion and retraction which can result in  
2 anatomical distortion of the vaginal cavity which can  
3 interfere with sexual intercourse. Clinical data  
4 suggest the risk of such an complication is increased  
5 in the case of associated hysterectomy. This must be  
6 taken in consideration when the procedure is planned in  
7 a sexually active woman."

8 Now, do you have an opinion as to whether or  
9 not that warning should or should not have been  
10 provided in the Prolift® IFU?

11 A. I have an opinion on it, yes.

12 Q. What is your opinion?

13 A. Absolutely, it should have been.

14 Q. Why do you say that?

15 A. Well, you have an individual, Arnaud, who  
16 knows the data, has seen what's happened with internal  
17 documentation, and he is warning -- he saw the problems  
18 that were occurring, knew about the problems and wants  
19 to put in the IFU a warning to doctors saying patients  
20 need to be told about this.

21 MR. ISMAIL: Objection, move to strike,  
22 improper expert testimony.

23 BY MR. SLATER:

24 Q. With regard to sexually active women, do

1     you have an opinion as to whether or not a warning was  
2     needed to cull out the specific risks for sexually  
3     active women?

4             A.     Absolutely, because of the risk of  
5     dyspareunia, yeah. You need to be able to tell them,  
6     you have a potential for problem and not be able to  
7     have intercourse without pain in the future.

8             Q.     Doctor, let's go back to the IFU, Exhibit  
9     P1005. You have it right there. Okay. Start over.

10            Doctor, looking at the IFU, let's look at the  
11   last page, and it has a list of adverse reactions.

12            Do you see that?

13            A.     Yes, I do.

14            Q.     And it says, "Potential adverse reactions  
15   are those typically associated with surgically  
16   implantable materials." I want to stop there.

17            Surgically implantable materials, is that  
18   limited -- is that group of materials just mesh, or is  
19   that a bigger group?

20            A.     Well, as they state there, surgically  
21   implantable materials is anything, that can be a heart  
22   valve, knee joint, hip joint. It could be anything.

23            Q.     In your opinion, is it accurate, medically  
24   accurate to say that for mesh, the Prolift® mesh in

1 actual use that the potential adverse reactions are  
2 those typically associated with surgically implantable  
3 materials in general?

4 A. No, not at all.

5 Q. Why do you say that?

6 A. I mean, the type of complication, the  
7 severity, the chronic nature, the progressive nature is  
8 different than in other types of implants. I do  
9 implants on different types of things in males. I'm  
10 the number one implanter in the United States, and we  
11 don't see what we're seeing with these females. So you  
12 can't -- you can't compare all surgical implants.  
13 We're dealing with a vaginal mesh.

14 Q. Let me read in the adverse reactions,  
15 there's certain language. They mention erosion and  
16 extrusion.

17 Do you see those? They're listed in that list  
18 of adverse reactions typically associated with  
19 surgically implantable materials?

20 A. Yes, I do.

21 Q. Is it adequate, in your opinion, from a  
22 medical standpoint to simply list erosion and  
23 extrusion, as done there, to communicate the risks of  
24 erosion and extrusion?

1 A. No, it's wholly inadequate.

2 Q. Why?

3 A. It's insufficient, it gives us no idea of  
4 the frequency, the severity, recurrent nature, the  
5 lifelong risk of erosions and extrusions.

6 Q. It says with regard to potential adverse  
7 reactions typically associated with surgically  
8 implantable materials "scarring that results in implant  
9 contraction."

10 Do you see that?

11 A. Yes, I do.

12 Q. Is that an adequate description of the  
13 risk of scarring and implant contraction?

14 A. No.

15 Q. Why is that?

16 A. Again, like I mentioned, it has no idea of  
17 the ramifications, the severity of it, the progressive  
18 nature of it, the life-changing disability and the  
19 inability to fix it.

20 Q. Doctor, let's go to the next Exhibit  
21 P1557. This is an e-mail written by David Robinson,  
22 October 28, 2005.

23 Are you familiar with this e-mail?

24 A. Yes, I am.

1           Q.    In this e-mail, David Robinson says he is  
2   aware of four cases of Prolift®s done in folks with  
3   normal preoperative voiding function who post Prolift®  
4   can't void.

5           Do you see that?

6           A.    Yes, I do.

7           Q.    He says a little further down, some have  
8   resolved spontaneously but have taken as long as a year  
9   to do so and asks the person he's writing to if they've  
10   seen the -- this complication, this is right before he  
11   joined the company as medical director?

12                   MR. ISMAIL:  Objection to the use of this  
13                   document as hearsay.

14   BY MR. SLATER:

15           Q.    Correct?

16           A.    Yes.

17           Q.    And David Robinson says -- and it's  
18   actually addressed to Marty, that would be Marty  
19   Weisberg, medical director, if this starts getting  
20   reported, it's going to scare the daylights out of  
21   doctors.

22           Do you see that?

23                   MR. ISMAIL:  Same objection.

24                   THE WITNESS:  Yes, I do.



1 BY MR. SLATER:

2 Q. From your standpoint as a physician in  
3 clinical practice and teaching residents and an author  
4 of articles, is that of significance to you?

5 MR. ISMAIL: Objection, hearsay, improper  
6 grounds for expert testimony.

7 THE WITNESS: Absolutely, yes.

8 BY MR. SLATER:

9 Q. Why is that significant to you?

10 MR. ISMAIL: Same objections.

11 THE WITNESS: Because it's true. We're  
12 trained not to harm people, make them worse.  
13 That's the whole goal of medicine. So now  
14 they're saying now they're trying to cover up a  
15 potential complication.

16 MR. ISMAIL: Move to strike,  
17 nonresponsive, 403, improper grounds for  
18 testimony.

19 BY MR. SLATER:

20 Q. Let me ask you this question: Where it  
21 says that if this starts getting reported that people  
22 were having the inability to void, they were having  
23 urinary retention that was lasting for a year or more  
24 and if it gets reported it's going to scare the

1     daylights out of doctors, why, in your opinion, is that  
2     significant?

3                     MR. ISMAIL: 403, cumulative, hearsay,  
4                     improper grounds for expert testimony.

5                     THE WITNESS: It's a unique complication  
6                     that would not necessarily be seen. You don't  
7                     see this with traditional repairs. So this is  
8                     a unique thing. They're talking bladder atony,  
9                     which means there's no function to the bladder,  
10                    so the nerves going to the bladder have been  
11                    disrupted by this procedure.

12    BY MR. SLATER:

13                    Q.    Does the IFU adverse reactions list warn  
14                    of urinary complications, such as retention or urinary  
15                    dysfunction due to the Prolift® itself?

16                    A.    No.

17                    Q.    Do you have an opinion as to whether or  
18                    not it should have?

19                    A.    Absolutely it should have.

20                    Q.    Okay. Let's go back to Exhibit P1306,  
21                    patient brochure. You have it up there from beginning  
22                    of the dep, it's right there, and I think -- let me  
23                    take a step back.

24                    Have you in your practice seen and used patient

1 brochures?

2 A. Yes.

3 Q. You understand or do you understand the  
4 use for which they're supposed to be made?

5 A. Yes, I do, and I give them out daily.

6 Q. I want to pull up a slide, the last slide,  
7 Prolift® patient brochure, and what we'll do is with  
8 the brochure in hand, we'll go through certain things  
9 that the brochure says.

10 MR. ISMAIL: Objection.

11 BY MR. SLATER:

12 Q. In the interest of time.

13 MR. ISMAIL: Objection, to the use of the  
14 document, 403, lack of relevance in this case.

15 BY MR. SLATER:

16 Q. Let's do this, looking at the brochure  
17 itself, Page 10. Let's take down the slide -- let me  
18 stop. Let's leave the slide up for a second. I want  
19 to ask you a question about the slide, Doctor.

20 Is this a summary of issues you have with the  
21 information provided in the brochure?

22 A. Yes.

23 Q. And are we going to now go through those  
24 issues specifically within the brochure?

1 A. Yes.

2 Q. Now let's go to the brochure.

3 MR. ISMAIL: Object to use of the slide on  
4 the same grounds.

5 BY MR. SLATER:

6 Q. Page 10, let me ask you this about the  
7 slide that we have up.

8 Do you have an opinion -- well, rephrase.

9 We'll come back to it. Stop. Let me clean this up.

10 Looking at the patient brochure, Page 10, it  
11 says "What is Gynecare Prolift®" at the very top. "A  
12 revolutionary surgical procedure using Gynecare  
13 Prolift® employs a specially designed soft mesh placed  
14 in the pelvis to restore pelvic support."

15 Do you have an opinion as to whether or not  
16 that is adequate and accurate information regarding the  
17 Prolift®?

18 MR. ISMAIL: Objection, lack of relevance,  
19 403.

20 THE WITNESS: Well, it's a long sentence.  
21 Certain parts of it are correct, other parts  
22 are incorrect.

23 BY MR. SLATER:

24 Q. Let's talk about it. Let's talk about

1 calling it a revolutionary surgical procedure. Is that  
2 statement, in your opinion, something that should be  
3 included here?

4 MR. ISMAIL: Objection, lack of relevance,  
5 403.

6 THE WITNESS: I think that is actually an  
7 acceptable statement. It was new, it was  
8 different, no one had done it before, and it  
9 was revolutionary, and therein lies the problem  
10 that many doctors don't know a thing about it,  
11 and so they have to be taught.

12 BY MR. SLATER:

13 Q. It says it was a specially designed  
14 supportive soft mesh.

15 Was that an accurate statement, to your  
16 knowledge?

17 MR. ISMAIL: Objection, 403, lack of  
18 relevance.

19 THE WITNESS: It's false.

20 BY MR. SLATER:

21 Q. And why is that?

22 A. Because it was designed for hernias, not  
23 vaginal meshes.

24 Q. When it refers to it as being soft mesh,

1 in actual use, does the mesh remain soft?

2 MR. ISMAIL: Objection, cumulative, 403,  
3 lack of relevance.

4 THE WITNESS: Well, that's what we  
5 discussed, in my own personal experience and  
6 review of the internal documents and papers,  
7 manuscripts, it does not stay soft. It gets  
8 firm, rigid.

9 BY MR. SLATER:

10 Q. On Page 10 under "What is Gynecare  
11 Prolift®," towards the bottom it says, it's "performed  
12 through very small incisions inside the vagina."

13 Do you see that? First paragraph right there  
14 under "What is Gynecare Prolift®," the second sentence.

15 A. Yes, I see it.

16 Q. Is the Prolift® only placed through very  
17 small incisions, or does that accurately describe the  
18 trocars and the cannulas?

19 MR. ISMAIL: Objection, lack of relevance,  
20 403.

21 THE WITNESS: Well, no, it's not only  
22 performed through the vagina. There are also  
23 obturator incisions, and the incision is  
24 variable from 2 to 4 to 5 centimeters, so it

1 depends how you want to define very small.

2 BY MR. SLATER:

3 Q. Doctor, with regard to the brochure, let's  
4 go to Page 13, and it says, "What are the risks? All  
5 surgical procedures present some risks. Although  
6 rare," and I'm going to stop there.

7 Do you have an opinion as to whether or not it  
8 is accurate to describe the risks with the Prolift® as  
9 rare?

10 MR. ISMAIL: Objection, lack of relevance,  
11 403.

12 THE WITNESS: It is wrong, incorrect.

13 BY MR. SLATER:

14 Q. Why do you say that?

15 MR. ISMAIL: Same objection.

16 THE WITNESS: It's just not my opinion,  
17 that's also Axel Arnaud. He says it's rather  
18 common.

19 MR. ISMAIL: Objection, move to strike,  
20 improper testimony.

21 BY MR. SLATER:

22 Q. It says at the bottom of the section What  
23 are the risks, there is a small risk of the mesh  
24 material becoming exposed into the vaginal canal."

1           Do you have an opinion as to whether or not  
2   that is an accurate statement?

3           MR. ISMAIL:  Objection, 403, lack of  
4   relevance.

5           THE WITNESS:  Yes, I do.

6  BY MR. SLATER:

7           Q.   And what is your opinion?

8           A.   False.

9           Q.   Why do you say that?

10          MR. ISMAIL:  Same objections.

11          THE WITNESS:  Based upon my clinical  
12          experience, the review of the medical  
13          literature and internal documents, the risk is  
14          actually very common.

15  BY MR. SLATER:

16          Q.   On Page 13, towards the bottom, under "Is  
17   Gynecare Prolift® right for me?"  It says, "Pelvic  
18   floor repair procedures with Gynecare Prolift® are  
19   appropriate for most patients."  I want to stop there.

20          Do you have an opinion as to whether that is an  
21   accurate statement?

22          MR. ISMAIL:  Lack of relevance, 403.

23          THE WITNESS:  Yes, I do.

24  BY MR. SLATER:



1 Q. And what is your opinion?

2 MR. ISMAIL: Same objection.

3 THE WITNESS: It's incorrect based upon  
4 the medical literature.

5 BY MR. SLATER:

6 Q. Why do you say that?

7 A. Because the inventors of the product and  
8 other researchers coming out saying it needs to be for  
9 high grade and recurrent prolapse.

10 MR. ISMAIL: Move to strike, hearsay.

11 BY MR. SLATER:

12 Q. Doctor, do you have an opinion as to  
13 whether or not the Prolift® patient brochure provides  
14 an accurate picture of the risk-benefit profile for the  
15 Prolift® for a doctor or a patient?

16 MR. ISMAIL: Objection, lack of relevance,  
17 403.

18 THE WITNESS: I have an opinion, yes.

19 BY MR. SLATER:

20 Q. And what is your opinion?

21 MR. ISMAIL: Same objection.

22 THE WITNESS: It is insufficient and  
23 inadequate.

24 BY MR. SLATER:

1           Q.     Doctor, with regard to the Prolift® IFU,  
2     do you have an opinion to a reasonable degree of  
3     medical certainty as to whether the IFU provides an  
4     adequate and accurate picture of the risk-benefit  
5     profile for the use of the Prolift®?

6           MR. ISMAIL:   Cumulative.

7           THE WITNESS:   I have an opinion, yes.

8     BY MR. SLATER:

9           Q.     What is your opinion?

10          MR. ISMAIL:   Same objection.

11          THE WITNESS:   It is insufficient and  
12          inadequate.

13     BY MR. SLATER:

14          Q.     And is that for with regard to the patient  
15     brochure, your opinion, is that based upon all the  
16     things you've told us during your testimony with regard  
17     to the nature of the Prolift® and the risks?

18          A.     Absolutely.

19          Q.     With regard to the IFU, is your opinion  
20     based upon the information you've given us throughout  
21     your testimony regarding the nature of the procedure,  
22     the risks and the other things you've told us about the  
23     Prolift®?

24          A.     Yes.

1 MR. SLATER: Let's go off.

2 THE VIDEOGRAPHER: The time is 12:24, and  
3 we're off the record.

4 (Brief recess.)

5 THE VIDEOGRAPHER: The time is 12:40 and  
6 we are back on the record.

7 MR. SLATER: Dr. Elliott, thank you very  
8 much. I think there will be some  
9 cross-examination from defense counsel.

10 CROSS-EXAMINATION

11 BY MR. ISMAIL:

12 Q. Good afternoon, Doctor.

13 A. Good afternoon.

14 Q. Are you prepared to proceed with  
15 cross-examination at this time?

16 A. Yes, I am.

17 Q. Doctor, you testified this morning about  
18 potential complications you believe that are associated  
19 with the use of transvaginal mesh for treatment of  
20 organ prolapse, correct?

21 A. Correct.

22 Q. Now, I will get to your general views  
23 later but, can you confirm that not every patient who  
24 received transvaginal mesh for treatment of prolapse

1 experienced one of the complications you described this  
2 morning?

3 MR. SLATER: Objection. You can answer.

4 THE WITNESS: At this point in time, as of  
5 November 21st, 2015, those patients -- not all  
6 patients have experienced all those  
7 complications.

8 BY MR. ISMAIL:

9 Q. And that's true for the Prolift® as well,  
10 right?

11 A. That is correct.

12 Q. Before anyone can conclude that a patient  
13 experienced any of the complications from a Prolift®  
14 device you would need to consider the specifics of that  
15 patient, correct?

16 A. You have to look at the entire patient,  
17 all the medical history and their surgical procedures,  
18 yes.

19 Q. Okay. So let's just make sure we're  
20 making ourselves clear here. So what you would want to  
21 look at to know whether a patient has experienced a  
22 complication from a Prolift®, you would want to look at  
23 patient medical records, correct?

24 A. That would be part of it, yes.

1 Q. You would want to consider what symptoms  
2 the patient reported and when, correct?

3 A. Chronology of onset of symptoms, yeah,  
4 that would be an important factor.

5 Q. You would want to consider, in this  
6 analysis that we're describing, what other procedures  
7 or surgeries that patient had in the relevant time  
8 frame, correct?

9 A. Yeah, you would want to look at the  
10 concurrent surgeries and past surgeries, yeah, that's  
11 right.

12 Q. You would want to consider the findings of  
13 that patient's healthcare provider with respect to the  
14 patient's symptoms and complaints, correct?

15 A. Well, that would be the medical records,  
16 yeah, with the caring physician's report, yes.

17 Q. And you have done none of that with  
18 respect to Patricia Hammons, correct?

19 A. Incorrect.

20 Q. Let me rephrase.

21 You did not disclose anywhere in your expert  
22 report any opinions relating to Ms. Hammons, correct?

23 A. I did -- not specific to Ms. Hammons, no.

24 Q. You did not disclose anywhere in your

1 expert report having reviewed Ms. Hammons' medical  
2 records, correct?

3 A. I don't recall if I have reviewed her  
4 records but I didn't -- not in the expert report I  
5 don't believe.

6 Q. You didn't disclose anywhere in your  
7 expert report that you reviewed the sworn testimony in  
8 this case, correct?

9 MR. SLATER: Objection.

10 BY MR. ISMAIL:

11 Q. The sworn testimony in Ms. Hammons' case,  
12 correct?

13 A. You mean her --

14 MR. SLATER: Let me just clarify. When  
15 you say in Ms. Hammons' case, you are talking  
16 about of her or --

17 MR. ISMAIL: I'll clarify.

18 THE WITNESS: Sworn testimony, you mean  
19 her deposition?

20 MR. ISMAIL: I will rephrase, Doctor.

21 THE WITNESS: Okay.

22 BY MR. ISMAIL:

23 Q. Nowhere in your expert report do you  
24 disclose that you reviewed the sworn testimony of

1 Ms. Hammons, correct?

2 A. I don't recall disclosing that, no.

3 Q. Nowhere in your expert report did you  
4 disclose reading the sworn testimony of Ms. Hammons'  
5 healthcare providers, correct?

6 A. I don't believe so. Again, I'd have to  
7 look at the report. I don't recall making that  
8 statement one way or the other actually.

9 Q. Nowhere in your expert report do you  
10 disclose doing a physical exam on Ms. Hammons, correct?

11 A. That would be correct, yes.

12 Q. And you have not done a physical exam on  
13 Ms. Hammons, correct?

14 A. No, I have not, no.

15 Q. So my statement is correct?

16 A. Yes.

17 Q. And you have previously said, Doctor, that  
18 a physical examination is one of the most important  
19 pieces of the puzzle in understanding what happened to  
20 a patient, correct?

21 A. That's a fair statement, yes.

22 Q. And certainly, Doctor, you can confirm  
23 that in some patients Prolift® was effective in  
24 relieving symptoms of the patient's pelvic organ

1 prolapse, correct?

2 A. That does happen at times, yes.

3 Q. And not just an improvement in the  
4 patient's symptoms, but, actually, a Prolift® can  
5 improve a patient's quality of life, that has been  
6 reported, correct?

7 A. That has been reported, yes.

8 Q. And before you can determine whether a  
9 patient has had an improvement in her quality of life  
10 you would want to look at the same things we have  
11 already discussed; the medical records, the timing of  
12 her symptoms, findings of her healthcare providers, et  
13 cetera, correct?

14 A. That is correct.

15 Q. And nowhere in your expert report do you  
16 disclose doing any of that analysis for Ms. Hammons,  
17 true?

18 A. I don't disclose that, you are correct.

19 Q. Now, you have discussed your views on  
20 Prolift® in response to questions from Mr. Slater this  
21 morning, right?

22 A. Yes.

23 Q. And you did so as a paid witness on behalf  
24 of the plaintiff lawyers, correct?



1 A. That is correct.

2 Q. You were first contacted in September of  
3 2011; do you recall that?

4 A. August, September of '11, yes.

5 Q. Okay. So I want the jury to understand  
6 your experience with Prolift® before the time that you  
7 were hired by the plaintiff lawyers in this litigation,  
8 okay?

9 A. Okay.

10 Q. Now, you, yourself, have never performed a  
11 Prolift® surgery for the implantation of a Prolift®,  
12 correct?

13 A. By choice, you are correct, yes.

14 Q. So when you were walking the jury through  
15 this morning, in the event that video is shown at  
16 trial, the surgery of a Prolift® being implanted in a  
17 patient, you never have done that yourself, correct?

18 A. That is correct, by choice I did not, yes.

19 Q. And that surgical video you never saw  
20 prior to being retained by the plaintiff lawyers in  
21 this litigation, correct?

22 A. That specific video I did not, you are  
23 correct.

24 Q. In fact, Doctor, you never received any

1 training whatsoever on Prolift®, true?

2 A. That would be correct, yes.

3 Q. You walked through or at least referenced  
4 a -- something that Mr. Slater introduced as a  
5 professional education PowerPoint.

6 Do you recall seeing that this morning?

7 A. Yes, I do.

8 Q. Prior to being hired by the plaintiff  
9 lawyers in this case you had never seen any  
10 professional education materials submitted by Ethicon  
11 on Prolift®, correct?

12 A. Not that I recall but I've been to  
13 their -- their Ethicon booth when this first came out,  
14 so I don't recall what I saw back then.

15 Q. When you say you went to the Ethicon  
16 booth, you are saying to the extent Ethicon had a booth  
17 at a medical conference, you might have stopped by --

18 A. Yeah.

19 Q. -- and you can't recall whether you saw  
20 anything on Prolift® in such visit; is that fair?

21 A. No. We would have seen it on the  
22 Prolift®. I don't recall what I saw. It was a long  
23 time ago. It was when it first came out.

24 Q. All right. Let me rephrase my question

1     then.

2                 You never attended any type of professional  
3     education courses that Ethicon sponsored for Prolift®,  
4     true?

5                 A.     You are correct, yes.

6                 Q.     Now, you never participated in any  
7     professional education courses sponsored by any  
8     manufacturer of a transvaginal mesh for treatment of  
9     pelvic organ prolapse, correct?

10                A.     Well, that -- that's what we clarified  
11     earlier. I was in attendance and an instructor AMS as  
12     far as with the sling and then went over and implanted  
13     their device on the cadaver. I was not a formal  
14     student because I was an instructor for slings, but,  
15     again, I just walked over to the next cadaver and did  
16     it.

17                Q.     All right. Let's make sure the jury  
18     understands what you are saying. When you are saying  
19     that's something that I clarified earlier, you recall  
20     saying something different in your sworn deposition  
21     testimony in this case?

22                A.     My deposition in 2011 or 2012 maybe the  
23     year was, I stated I was never a formal student in any  
24     class, which is correct. I was not a formal student.

1 That's why how do we define it? I was not a formal  
2 student, I did not take a formal class but I have  
3 implanted with the instructor there so I don't know how  
4 we define myself, to be clear.

5 Q. All right. Let me just break that down  
6 into chunks if you don't mind, Doctor.

7 Previously when you were asked whether you  
8 attended any professional education training for a  
9 transvaginal mesh for pelvic organ prolapse your answer  
10 was that you had not, correct?

11 A. Which would be correct, yes.

12 Q. And what you are trying to clarify is that  
13 while you were at a training for a different medical  
14 device, you went over to some training happening on a  
15 transvaginal kit for -- by a different manufacturer?

16 A. By AMS, that's correct.

17 Q. Okay. So even with the clarification that  
18 you have added today, it's still true that you have  
19 never attended any professional education for Prolift®?

20 A. Correct.

21 Q. And your answer you referenced cadaver  
22 training. Can you please tell us what cadaver training  
23 is?

24 A. It would be a workshop using a non-live

1 human cadaver, fresh frozen cadaver, where you just  
2 have the pelvis to work with to insert the trocars  
3 through the obturator foramen, vaginal dissection and  
4 those types of things.

5 Q. And cadaver training is sometimes used for  
6 surgeons to gain familiarity with a new surgical  
7 procedure?

8 A. Correct.

9 Q. And you had never done any cadaver  
10 training on Prolift®, correct?

11 A. Correct.

12 Q. Now -- one second, Doctor.

13 Here's my question, at the time of your  
14 deposition you testified that you never underwent any  
15 cadaver lab training with respect to transvaginal  
16 placement of mesh, and you still stand behind that  
17 comment, true?

18 A. That's correct. Again, it's a matter of  
19 defining how we define what I did.

20 Q. Now, before being hired by the plaintiff  
21 lawyers in this case you had never observed a surgery  
22 involving Prolift®, correct?

23 A. Probably would be accurate, yes.

24 Q. Now, you have no research experience on

1 Prolift® as well; isn't that true, Doctor?

2 A. Correct.

3 Q. You have never participated in any  
4 clinical trials that relate to Prolift®, true?

5 A. Specific Prolift®, you are correct, yes.

6 Q. You haven't participated in any clinical  
7 trials relating to transvaginal mesh or the use of  
8 transvaginal mesh in the treatment of pelvic organ  
9 prolapse; isn't that correct, Doctor?

10 A. Correct.

11 Q. You have never done any -- withdrawn.

12 You referenced earlier something called Level 1  
13 evidence; do you recall making that reference?

14 A. I don't recall but I don't doubt I said  
15 it.

16 Q. Is randomized controlled clinical trials  
17 an example of Level 1 evidence?

18 A. Yes.

19 Q. You have never been involved in any  
20 randomized controlled clinical trials involving the use  
21 of mesh in any application, correct, Doctor?

22 A. Meshes, you would be correct, yes.

23 Q. You've never been involved in any clinical  
24 study that used transvaginal mesh to treat pelvic organ

1 prolapse, true?

2 A. Transvaginal meshes, I don't recall. No,  
3 I don't believe so.

4 Q. So my statement is correct?

5 A. Yes.

6 Q. You've never been involved in any  
7 prospective studies involving the use of mesh, correct?

8 A. Correct.

9 Q. You have never been involved in a clinical  
10 trial designed to evaluate the safety and efficacy of a  
11 transvaginal mesh in any application, correct?

12 A. Correct.

13 Q. Are you familiar with meta-analyses,  
14 Doctor?

15 A. Yes.

16 Q. Can you please tell us what they are?

17 A. Meta-analysis is just a statistical way of  
18 analyzing multiple different studies, studies you have  
19 not performed but using other people's datas and  
20 analyzing them.

21 Q. Are meta-analyses a way that researchers  
22 can summarize the clinical evidence that have been  
23 published on a surgery?

24 A. Possibly.

1 Q. You have not done any meta-analyses  
2 involving the use of transvaginal mesh, true?

3 A. Correct.

4 Q. You indicated, Doctor, a couple times that  
5 you currently practice at Mayo in Minnesota?

6 A. Correct.

7 Q. You're not here today testifying as a  
8 representative of the Mayo Clinic; isn't that correct,  
9 Doctor?

10 A. That would be -- I guess accurate, yes.

11 Q. Mayo has not sanctioned your activities  
12 working as a paid witness on behalf of the plaintiff  
13 lawyers in this case, true?

14 MR. SLATER: Objection.

15 THE WITNESS: No, this is on my private  
16 time.

17 BY MR. ISMAIL:

18 Q. In fact, the Mayo Clinic does not even  
19 know that you are serving as an expert for the  
20 plaintiffs in this case, correct?

21 A. As I stated, it's all in my private time.

22 Q. So the answer to my question is what, sir?

23 A. That is correct, it's all in my private  
24 time.



1           Q.    I'm trying to make a distinction, Doctor,  
2    between you saying it's on your private time and  
3    whether your hospital even knows you are doing this  
4    activity, so let me restate the question so you have it  
5    in mind.

6           The Mayo Clinic does not even know that you are  
7    serving as an expert on behalf of the plaintiffs in  
8    this litigation, true?

9           A.    That is correct, it is all done in my  
10   private time.

11          Q.    Have you disclosed to the Mayo Clinic the  
12   money you have received from the plaintiff lawyers in  
13   this litigation?

14          A.    No, I have not.

15          Q.    But you have, in fact, received money from  
16   the plaintiff lawyers in this case, correct?

17          A.    That is true.

18          Q.    How much per hour are you being paid, sir?

19          A.    700.

20          Q.    When you say "700", that's \$700 per hour?

21          A.    Correct.

22          Q.    How much has Mr. Slater paid you thus far?

23               MR. SLATER:  You are talking about in this  
24   case?

1 BY MR. ISMAIL:

2 Q. I'm asking how much Mr. Slater has paid  
3 you since the time Mr. Slater began paying you.

4 A. I have no idea. I don't even bill  
5 Mr. Slater.

6 Q. Whom do you bill?

7 A. Mr. --

8 MR. SLATER: Let's take a step back here.  
9 There's an understanding that witnesses are to  
10 be questioned about the fees they're paid in a  
11 particular case and that's how it's been done  
12 throughout and that's been our understanding in  
13 this case. You may not be aware of that but  
14 it's been how it's been handled in the  
15 depositions and that was our understanding.

16 So if you are asking about in the Hammons  
17 case, you know, that's fine, but to start  
18 talking about overall litigation or other  
19 cases, it's understood and it's on the record,  
20 probably in the deposition of Dr. Weber, that  
21 we were not going to get into billing outside  
22 the specific case.

23 MR. ISMAIL: Well --

24 MR. SLATER: And, in fact, that's how it

1           was handled in the Bellew trial in the MDL and  
2           I think that's the understanding everybody has  
3           about how we're handling this on both sides.

4           MR. ISMAIL: So how about he gives the  
5           answer -- since we're not going to call him  
6           back here and redo this, he gives the answer  
7           and if we don't play it to the jury, we don't  
8           play it to the jury.

9           MR. SLATER: I'm not going to allow him to  
10          testify beyond what he's been paid in this case  
11          because we have an agreement between counsel  
12          and I'm not going to have someone walk in on  
13          cross-examination and change the ground rules  
14          in the middle of cross.

15          MR. ISMAIL: That's not an agreement to  
16          which I am privy.

17          MR. SLATER: You are bound to it though,  
18          co-counsel --

19          MR. ISMAIL: Can I finish my statement?  
20          Not an agreement to which I -- that I've heard  
21          of and so I'm going to ask the question and  
22          it's up to you as to whether you are going to  
23          let him answer.

24          MR. SLATER: I will only allow him to

1           answer questions about what he's been paid in  
2           this case, so you don't need to ask the  
3           questions as a formality because I'm not going  
4           to allow him to answer them because we have an  
5           agreement with counsel.

6                   MR. ISMAIL: I'm going to ask the question  
7           and you can do what you want.

8   BY MR. ISMAIL:

9           Q. Dr. Elliott, how much have you been paid  
10   by the plaintiff lawyers who are suing Ethicon?

11                   MR. SLATER: Don't answer the question and  
12           the question is improper anyway.

13   BY MR. ISMAIL:

14           Q. Are you going to refuse to answer the  
15   question, Doctor?

16                   MR. SLATER: No, no, you are not even  
17           going to ask him that --

18                   MR. ISMAIL: Yes.

19                   MR. SLATER: -- because I have instructed  
20           him not to.

21                   MR. ISMAIL: He has to right to -- you  
22           have given your instruction, he can still  
23           answer the question if he wants.

24                   THE WITNESS: I'm following Mr. Slater's

1                   advice to not answer the question.

2                   MR. ISMAIL: I will limit my question.

3 BY MR. ISMAIL:

4                   Q. How much have you been paid with respect  
5 to your work on behalf of the plaintiff lawyers in the  
6 Prolift® litigation?

7                   MR. SLATER: Objection, same thing, don't  
8 answer.

9 BY MR. ISMAIL:

10                  Q. Are you going to refuse to answer my  
11 question, Doctor?

12                  A. I'm not going to answer based on  
13 Mr. Slater's recommendation.

14                  Q. Isn't it true, Doctor, you submit an  
15 invoice every month for your work on behalf of the  
16 plaintiffs' lawyers and you have since 2011?

17                  MR. SLATER: Objection.

18                  THE WITNESS: Well, not every month, only  
19 if work is done.

20 BY MR. ISMAIL:

21                  Q. How many of the months since 2011 have you  
22 submitted an invoice?

23                  MR. SLATER: Objection. All these  
24 questions he's -- obviously, these are back

1 door -- I'm going to object to the whole line  
2 of questions. I mean, it's generalized about  
3 how often he submits invoices is fine, but I  
4 object to this.

5 I mean, sir, there's an agreement between  
6 counsel. It's a little frustrating when  
7 someone walks in and says, well, sorry, I  
8 wasn't there. Maybe they need to prep you  
9 better.

10 BY MR. ISMAIL:

11 Q. And your answer, sir?

12 A. Oh, I have no idea, looking back, of how  
13 many times I do and don't because there are sometimes I  
14 don't do any work for months.

15 Q. Doctor, have you estimated that you have  
16 on average spent 20 to 30 hours a month working on  
17 behalf of the plaintiff lawyers in this litigation?

18 MR. SLATER: Objection. Now --

19 MR. SPECTER: What's "this litigation"?  
20 Beyond that.

21 MR. ISMAIL: You can state your objection,  
22 you can instruct him not to answer. We don't  
23 have to argue about it. If it doesn't get  
24 played, it doesn't get played.

1 MR. SLATER: But it's not the point  
2 because if it doesn't get played, it doesn't  
3 get played is not really a legitimate answer to  
4 that because you are creating a record of  
5 things that we had an agreement were not going  
6 to be asked about.

7 MR. ISMAIL: And if you're right what's  
8 the --

9 MR. SLATER: And it goes both ways, by the  
10 way. Your experts don't want to be asked these  
11 questions either.

12 MR. ISMAIL: If you're right, you're  
13 right. I still don't understand what the --  
14 you make your objection and instruct him not to  
15 answer. I don't understand why we're even  
16 arguing about it.

17 MR. SLATER: Well, because it's  
18 frustrating that -- you know, you are  
19 pretending you don't know there was an  
20 agreement.

21 BY MR. ISMAIL:

22 Q. So let me restate the question so you have  
23 it in mind, Doctor.

24 A. Thank you.

1           Q.    Have you worked on average 20 to 30 hours  
2   a month on behalf of the plaintiff lawyers since  
3   approximately 2011?

4           MR. SLATER:  Objection.

5           MR. SPECTER:  Can I ask you to clarify  
6   though, counsel.  Are you asking about the  
7   Hammons litigation or are you asking about the  
8   litigation in general?

9           MR. ISMAIL:  Well, since the Hammons  
10   litigation wasn't filed in 2011, I suspect that  
11   would be difficult.

12          MR. SLATER:  Yeah, well, no one knows  
13   that.

14          MR. SPECTER:  The jurists know that,  
15   counsel.  Please.

16          MR. ISMAIL:  So the question is there.  If  
17   you don't want him to answer --

18          MR. SPECTER:  I'm just asking you to  
19   clarify your question, counsel.  Are you asking  
20   about the Hammons litigation or are you asking  
21   about litigation in general?

22          MR. ISMAIL:  My question goes to the issue  
23   of bias, the amount of money the witness has  
24   been paid and if you don't want him to answer



1 the question, tell him not to answer the  
2 question.

3 MR. SPECTER: I'm not asking about what  
4 the question goes to. I'm simply asking  
5 whether the question goes to the Hammons  
6 litigation or the TVM litigation in general.

7 I take it from what you are saying you are  
8 asking about the TVM litigation in general?

9 MR. ISMAIL: I'll rephrase.

10 BY MR. ISMAIL:

11 Q. Doctor, the report that you submitted in  
12 this case, in Ms. Hammons' case, does that date back to  
13 work that you started doing on behalf of the plaintiff  
14 lawyers when you were first retained in 2011?

15 MR. SLATER: Objection. You can answer.

16 THE WITNESS: I don't quite know how to  
17 answer that question. Not to be evasive by any  
18 means, I've been doing work for the past 20  
19 years on prolapse and complications so that  
20 specific document, I probably have done work  
21 earlier that was translated to it as far as the  
22 background and those types of things, but,  
23 again, I can't be specific. I just don't know.

24 BY MR. ISMAIL:

1 Q. I'll rephrase.

2 You have looked at materials that were sent to  
3 you by the plaintiff lawyers in this case, correct?

4 A. Correct.

5 Q. Mr. Slater has sent you materials,  
6 correct?

7 A. Yes.

8 Q. You have looked at some internal  
9 depositions and documents about the Ethicon employees,  
10 correct?

11 A. Yes.

12 Q. And you have referenced them during your  
13 testimony today?

14 A. That is correct.

15 Q. And you have included them in your expert  
16 report submitted in this case?

17 A. That is correct.

18 Q. Some of the work that you did that  
19 resulted in the expert report submitted in Ms. Hammons'  
20 case dates back to 2011/2012 time frame, correct?

21 A. That would be correct, yes.

22 Q. So with that understanding, Doctor, can  
23 you tell me the amount of money that you have been paid  
24 by the plaintiff lawyers for that work?

1 MR. SLATER: Objection. Don't answer the  
2 question.

3 THE WITNESS: I'm not going to answer the  
4 question based on Mr. Slater's recommendation.

5 BY MR. ISMAIL:

6 Q. Doctor, Prolift® was designed to treat  
7 pelvic organ prolapse, correct?

8 A. That is correct.

9 Q. Since we're not exactly sure when the jury  
10 is going to see this video, I don't know if this has  
11 been defined for them yet, but for the benefit of the  
12 jury, pelvic organ prolapse, in a general sense, when  
13 one or more of the patient's internal organs drop into  
14 the vagina?

15 A. Correct.

16 Q. Their internal organs most often involved  
17 include the bladder, the rectum, the uterus and the  
18 small bowel, correct?

19 A. Yes, that would be correct.

20 Q. And I think you told us earlier that what  
21 leads to a pelvic organ prolapse is a weakening of the  
22 patient's tissues in the pelvic floor, correct?

23 A. A weakening, a stretching of the tissues  
24 that hold it up, yes.

1 Q. Now, there are many risk factors that can  
2 lead to pelvic organ prolapse, correct?

3 A. There are several, yes.

4 Q. These include age, that's a risk factor,  
5 right?

6 A. Yes.

7 Q. Obesity I think you told us earlier was a  
8 risk factor?

9 A. Yes.

10 Q. Childbirth is a risk factor?

11 A. Correct.

12 Q. Previous surgery for prolapse is a risk  
13 factor?

14 A. Yes.

15 Q. Previous hysterectomy is a risk factor?

16 A. Possible, yes.

17 Q. Menopause?

18 A. Menopause would be questionable. It's  
19 going to be tough to delineate that data because we  
20 also have age and menopause, so it's -- it's not  
21 helpful, let's put it that way.

22 Q. Fair enough. And what you are saying is  
23 age and menopause often go hand-in-hand and it's  
24 difficult to tease out which is the menopause and which

1 is the age?

2 A. Correct.

3 Q. Repeated lifting can be a risk factor for  
4 pelvic organ prolapse?

5 A. That's correct.

6 Q. Smoking has been reported as a risk factor  
7 for pelvic organ prolapse?

8 A. Again, there is going to be studies out  
9 there maybe yes, maybe no, but it's possible.

10 Q. And, of course, a woman can develop pelvic  
11 organ prolapse with just one or even none of the risk  
12 factors we've just described, correct?

13 A. That is correct, yeah, with just one, yes.  
14 With none it's rare, but it does occur.

15 Q. Now, pelvic organ prolapse is assessed on  
16 a grading scale for how severe the prolapse is,  
17 correct?

18 A. Yeah, how severe the anatomical prolapse  
19 is, yes.

20 Q. And there -- I think you reference there's  
21 a few different grading systems that are out there for  
22 clinicians to use, right?

23 A. There's three or four, yes.

24 Q. One of which I think you reference was

1     called the POP-Q system?

2             A.     Correct.

3             Q.     Have you ever used the POP-Q system  
4     yourself?

5             A.     I use it not as commonly as the  
6     Baden-Walker.

7             Q.     Does the POP-Q system assess how far the  
8     woman's internal organs have descended into or beyond  
9     the opening of the vagina?

10            A.     That's part of it, yes.

11            Q.     What are the grading -- I don't need the  
12     definitions yet, but is it -- it's grades 1 through 4,  
13     correct?

14            A.     Yeah, but then you are looking at each  
15     component, whether it's anterior, posterior, apical,  
16     vaginal length, so it's -- yeah, you can do the 1, 2,  
17     3, 4 but that's gonna -- simplified form of the POP-Q.

18            Q.     And 4 is the most severe grade of pelvic  
19     organ prolapse?

20            A.     That is correct.

21            Q.     The other system you reference is the  
22     Baden-Walker system; is that correct?

23            A.     There's Baden-Walker and there's also  
24     International Continence Society stages. They're all

1 somewhat similar with different bells and whistles one  
2 way or the other.

3 Q. And the Baden-Walker, again, is grades 1  
4 through 4, with 4 being the worst?

5 A. That's correct.

6 Q. And that's the one that you prefer in your  
7 clinical practice?

8 A. Correct.

9 Q. What is the criteria for grade 4 under the  
10 Baden-Walker system?

11 A. Same as for the POP-Q, it's complete  
12 eversion out of the vagina.

13 Q. When you say "eversion" --

14 A. Means that the vagina has -- everted  
15 means -- think of the vagina like a tube sock; somebody  
16 reaches in, grabs it and everts out, eversion of the  
17 vagina.

18 Q. And in a grade 4, that is the most severe  
19 pelvic organ prolapse a physician can grade for a  
20 patient?

21 A. That is correct, yes.

22 Q. And in clinical application that means the  
23 prolapse is actually visible in the vaginal opening,  
24 correct?

1           A.     Correct. It can also be visible in stage  
2     2 also, but, yes, it's like a baby's head coming out of  
3     the vagina, basically.

4           Q.     Prolapse can be a serious condition for a  
5     woman, correct?

6           A.     It depends how you define serious. It can  
7     be bothersome. It's very rarely in the United States  
8     life-threatening, so it's not along the lines of a  
9     cardiac problem that's life and death. Very rarely,  
10    I've never seen that.

11          Q.     You used the description several times  
12    today of prolapse being a quality of life condition?

13          A.     Correct.

14          Q.     Meaning that a pelvic organ prolapse can  
15    negatively affect a woman's quality of life?

16          A.     That is correct, it can.

17          Q.     A pelvic organ prolapse can be  
18    debilitating and troublesome to a woman?

19          A.     Yeah, again, debilitating, yes, that can  
20    happen. It can be bothersome. I think it's fair to  
21    say it's bothersome.

22          Q.     The symptoms that a woman can report  
23    include feelings heaviness or pressure, correct?

24          A.     That is something they can feel, yes.



1           Q.    You've heard of reports of a woman feeling  
2   a bulge or seeing the protrusion from the vagina as a  
3   result of the pelvic organ prolapse, correct?

4           A.    That is correct, yes.

5           Q.    Difficulty with walking or sitting have  
6   been described in women with pelvic organ prolapse,  
7   correct?

8           A.    In severe cases, yes, that does happen.

9           Q.    And what we're describing here can be  
10   distressing to many women?

11          A.    Yeah, depends how you want to define many,  
12   but a lot of women it can be bothersome, I won't deny  
13   that at all. I agree with you.

14          Q.    Let me put it this way, Doctor, you would  
15   agree that prolapse can be significant enough that the  
16   patient doesn't want to deal with it?

17          A.    That is correct, yes.

18          Q.    You've used this term, dyspareunia, in  
19   your testimony. That, in a general sense, means pain  
20   with sexual intercourse, correct?

21          A.    That is correct.

22          Q.    There are some women for whom pelvic organ  
23   prolapse can actually cause dyspareunia, correct?

24          A.    That is correct. We have to define how

1     severe that dyspareunia is. There's not just --  
2     dyspareunia means only one thing, it can be severity,  
3     so I agree with you.

4             Q.     So seeing the description of a patient as  
5     having dyspareunia doesn't tell you how severe the  
6     dyspareunia is, correct?

7             A.     All it says is like you drive a car, we  
8     have no idea of the specifics of it, but it states that  
9     there is discomfort with sexual activity.

10            Q.     And, again, without regard to severity,  
11     you've confirmed for us already that women with pelvic  
12     organ prolapse can have dyspareunia, correct?

13            A.     To a certain degree, yes, they can.

14            Q.     Now, there are I guess a couple different  
15     reasons why a woman may not be sexually active who is  
16     experiencing pelvic organ prolapse, one of which can be  
17     just the pain that pelvic organ prolapse may result for  
18     dyspareunia, correct?

19            A.     Correct.

20            Q.     And the prolapsing organ in a woman can  
21     actually interfere with sexual activity, correct?

22            A.     It can block it, yes.

23            Q.     But, also, you are aware, Doctor, that for  
24     some women the prolapse affects how they feel about

1 themselves and embarrassment being with their partner  
2 or their desire to have sexual intercourse, correct?

3 A. I agree, the psychological aspect of  
4 embarrassment can be a significant issue.

5 Q. And you are aware, Doctor, that apart from  
6 the dyspareunia and the interference with sexual  
7 activity, pelvic organ prolapse symptoms can include  
8 pelvic pain or voiding problems?

9 A. It can and -- yeah, the voiding problems,  
10 in severe cases, it can do that. The other aspect of  
11 it you said is --

12 Q. Pelvic pain?

13 A. Pelvic pain, yeah, that can -- the usual  
14 thing I get is described as an aching, even a low back  
15 pain because of the prolapse.

16 Q. And when we say voiding complaints, that  
17 would include difficulty urination?

18 A. In severe cases of anterior prolapse,  
19 yeah, you can trouble as far as emptying the bladder.  
20 I very rarely see that but it has been described, yes.

21 Q. And so as you and I just went over for the  
22 jury a variety of complications that a woman can  
23 experience from a pelvic organ prolapse can result in a  
24 woman seeking out medical care to get that repaired,

1 correct?

2 A. That is correct, yes.

3 Q. And, in fact, I think you've told us  
4 before pelvic organ prolapse is a condition for which  
5 women have sought treatment for thousands of years?

6 A. I think I stated before as long as women  
7 have been having babies, they have been having problems  
8 with this, yes.

9 Q. And as long as there have been doctors who  
10 are concerned about caring for women, doctors have been  
11 trying to come up with good, satisfactory ways to treat  
12 a woman's pelvic organ prolapse, correct?

13 A. That is correct, yes, sir.

14 Q. And I think you told us that the treatment  
15 options for pelvic organ prolapse include conservative  
16 measures and surgical options as well, right?

17 A. Correct.

18 Q. One conservative measure you told us about  
19 was a wait and see approach?

20 A. Correct, observation, yeah.

21 Q. Another -- you used this term -- a  
22 pessary, right?

23 A. That's correct.

24 Q. And I think you told us that was a plastic

1 device that can be inserted into the vagina as a way to  
2 sort of prop up the falling organ?

3 A. Correct.

4 Q. Now, pessaries are not appropriate for all  
5 patients, you agree with that, right?

6 A. They might not work in all patients. As  
7 far as it being appropriate or not, in the rare case of  
8 some vaginal erosion, you wouldn't want to put anything  
9 in there. I would think the better statement would be  
10 they don't work in all patients.

11 Q. Fair enough. So the distinction you are  
12 drawing is a doctor, when considering how to treat a  
13 woman with a prolapse, would include a pessary on the  
14 list and then make a decision whether it's a good or  
15 bad idea here?

16 A. That would be fair to state, yes.

17 Q. Some women don't want to use a pessary,  
18 right?

19 A. Correct.

20 Q. If a woman receives a pessary, she has to  
21 be followed up periodically with her physician,  
22 correct?

23 A. Correct, yes.

24 Q. You have seen reports of vaginal discharge

1 with a pessary, right?

2 A. That is correct.

3 Q. You've seen reports of vaginal odor with a  
4 pessary?

5 A. Correct.

6 Q. There have been reports of ulceration with  
7 pessaries, correct?

8 A. That's correct.

9 Q. Obviously, that can lead to pain for the  
10 patient?

11 A. It could be, which you take out the  
12 pessary and that resolves itself.

13 Q. There can be bleeding associated with a  
14 pessary?

15 A. Along, yeah, with vaginal erosion that can  
16 happen.

17 Q. Tissue erosion?

18 A. It can, all those things, yeah.

19 Q. The symptoms that we've just described  
20 that can result from a pessary may lead a woman to  
21 discontinue the use of the pessary, right?

22 A. That is correct, yes.

23 Q. Of course, it's reasonable to believe that  
24 or to expect that a woman who has had a problematic

1 experience with a pessary that caused her  
2 complications, she would be less likely to accept that  
3 treatment again in the future?

4 A. I agree with you.

5 Q. And you don't actually even deal with  
6 pessaries yourself in your clinical practice, correct?

7 A. Yeah, you're correct. We discuss it. If  
8 we feel a patient is a good candidate for it, I send  
9 them to my GYN colleagues.

10 Q. We've been discussing a pessary as one of  
11 the conservative ways to treat a prolapse but you would  
12 agree that most of the time prolapse cases treated  
13 conservatively, the condition does not get better?

14 A. Yeah, though it -- prolapse does not  
15 frequently or rarely would get better. It usually  
16 stays the same or worsens.

17 Q. So you would agree, Doctor, with the  
18 statement that absent surgery, pelvic organ prolapse  
19 tends not to improve?

20 A. In general, that would be a fair  
21 statement.

22 Q. Now, there have been multiple types of  
23 surgeries trying to fix the problem of a prolapse,  
24 right?

1 A. Correct.

2 Q. Some of those surgeries have been around a  
3 long, long time?

4 A. That is correct.

5 Q. And over the years some surgeries have  
6 been more effective than others?

7 A. Correct.

8 Q. Different doctors use different approaches  
9 depending on their own experience, skill level, their  
10 comfort level as to which surgical option that  
11 physician prefers, correct?

12 A. That's correct.

13 Q. Transvaginal mesh was developed as one of  
14 the options for doctors to use to treat women with  
15 pelvic organ prolapse?

16 MR. SLATER: Objection.

17 THE WITNESS: Correct, yes.

18 BY MR. ISMAIL:

19 Q. One of the surgeries you described for us  
20 earlier as one of the surgical options was native  
21 tissue repair surgeries; do you recall making reference  
22 to that?

23 A. Correct, that's traditional colporrhaphy,  
24 yes.



1 Q. So there are different types of  
2 colporrhaphy procedures depending on which type of  
3 prolapse the patient has, correct?

4 A. Dependent upon the anatomical location,  
5 yes.

6 Q. So if --

7 A. Well, it's only going to be anterior and  
8 posterior, that's the only colporrhaphies.

9 Q. So anterior being a bladder prolapse?

10 A. Correct.

11 Q. And posterior being a rectal prolapse?

12 A. Correct.

13 Q. And the idea behind a colporrhaphy is that  
14 the surgeon is using the patient's own tissues and  
15 sutures as a way to prop up the descending organ,  
16 correct?

17 A. Yeah, you are correct, it's a plication or  
18 a bringing together of the tissues that have separated  
19 or thinned.

20 Q. One of the perceived problems with that  
21 type of surgery, the native tissue surgery, going back  
22 to say the 1990s, was that there were recurrences or  
23 failures of that type of surgery, correct?

24 A. Yeah, recurrence or failure can happen

1 with any surgery, it can happen with those, yes.

2 Q. And particularly, Doctor, my question is  
3 more of a historical one. If you go back to the period  
4 of time in the 1990s there was a feeling in the medical  
5 community that native tissue surgeries for treatment of  
6 prolapse had a high rate of failure?

7 A. I think the best way to say it is we  
8 didn't want to have any failure. I was a resident  
9 during that time, in training. We didn't want to have  
10 any failure so there was the pursuit of trying to find  
11 something that had a less failure rate.

12 Q. The -- historically the assessment of what  
13 was a success or a failure focused on the anatomical  
14 outcome, correct?

15 A. Historically that was one of the main  
16 features of it, yes.

17 Q. And I think you described for us today  
18 that the success or failure of a prolapse surgery can  
19 be measured either anatomically or by a review of the  
20 patient's symptoms, correct?

21 A. It depends, yeah. When you are doing a  
22 study you are going to say this is an anatomical study  
23 or a functional study or both. But, yeah, there's  
24 different ways of looking at it, but the tradition --

1 now you've got to look at function.

2 Q. And my question wasn't just in the context  
3 of a study but also with regard to a doctor treating a  
4 patient, the doctor can and will assess anatomic  
5 function and can and will assess symptomatic function,  
6 correct?

7 A. Yeah, you can assess it but what you care  
8 about is the patient happy or not.

9 Q. And when we're talking anatomic recurrence  
10 of a prolapse, we mean the surgeon can -- in examining  
11 the patient, has assessed that the prolapsed organ has  
12 redescended to a certain degree following the surgery,  
13 correct?

14 A. That's part of the assessment, yes.

15 Q. And anatomic recurrence of the prolapse  
16 was a concern because it exposed women to the risk of  
17 incurring the same prolapse symptoms again, right?

18 A. Possibly, yes.

19 Q. And I think just so we're focusing on the  
20 period of time before Prolift® was developed, you would  
21 agree that historically anatomic recurrence was a  
22 concern to doctors treating women with pelvic organ  
23 prolapse?

24 A. I think initially, yes, you are right and

1 then there became the shift overlooking at is the happy  
2 patient, quality of life.

3 Q. It was the recurrence concern that led  
4 doctors and surgeons to begin to experiment with the  
5 use of mesh to reinforce the pelvic floor, correct?

6 A. I think that's fair, yes.

7 Q. And at the time that Prolift® was under  
8 development you were familiar with the reports that  
9 nonmesh surgical repairs of prolapse had failures up to  
10 30 to 40%?

11 A. Yeah, but, again, you got to look at what  
12 paper that is. Are they looking at stage 2 being  
13 abnormal, you know, there is a debate now that is  
14 within the realm of normal, so you have to look at the  
15 specific studies, but those reports are out there. I  
16 don't agree with them and we don't now agree with it,  
17 but I agree there are reports out there.

18 Q. So, again, this question is going back to  
19 the time before the Prolift® was developed, you're  
20 aware that there was a concern that there was an  
21 unacceptably high failure rate with native tissue  
22 surgeries?

23 A. I think some people had those. Again, I  
24 didn't have those concerns.

1 Q. You were in training at the time, right?

2 A. Yeah. Well. Depends when you are  
3 talking.

4 Q. 1990s?

5 A. Yeah, '93 to '99 -- '93 to 2000.

6 Q. And some of the work that was done that  
7 assessed the success or failure of native tissue  
8 surgery was actually under the direction of the NIH,  
9 right?

10 A. Correct, you know, A lot of people were  
11 looking at it, yes.

12 Q. And so by that I mean there were  
13 researchers who were concerned about the failure rate  
14 of native tissue surgery outside of industry or  
15 manufacturers, that's fair to say?

16 A. Oh, yeah, I mean, doctors were very  
17 concerned about it. We wanted to get that recurrence  
18 rate down to zero.

19 Q. So one of the initial uses of mesh in the  
20 treatment of pelvic organ prolapse was through an  
21 abdominal surgery, correct?

22 A. The sacrocolpopexy has been around a long  
23 time, yes.

24 Q. And I think you told us earlier that the

1 mesh used in Prolift® is a polypropylene mesh?

2 A. Correct.

3 Q. And mesh used in the abdominal  
4 sacrocolpopexy also is polypropylene mesh, correct?

5 A. It can be and the one I use is.

6 Q. Most often the mesh used in abdominal  
7 sacrocolpopexy, is it polypropylene mesh?

8 A. I can't speak to everyone out there, some  
9 people have used cadaveric tissue and that is becoming  
10 more common now but it's -- again, I don't know. I  
11 would suspect there's more polypropylenes than anything  
12 else.

13 Q. Polypropylene has been used in surgical  
14 procedures for decades, correct?

15 A. That is correct.

16 Q. Polypropylene is used in sutures, some  
17 sutures, correct?

18 A. That is correct.

19 Q. And the use of polypropylene sutures goes  
20 back many decades, true?

21 A. Correct.

22 Q. You indicated that polypropylene was used  
23 in a hernia mesh; do you recall saying that earlier?

24 A. That's correct.

1 Q. The use of polypropylene hernia meshes  
2 goes back many decades as well, correct?

3 A. It's been around a long time, yes. Has a  
4 well-established track record.

5 Q. Historically the abdominal sacrocolpopexy  
6 was an open abdominal procedure, correct?

7 A. That is correct.

8 Q. Where a long incision would be made into  
9 the abdomen?

10 A. Well, it depends how you define long.  
11 From the umbilicus to -- the belly button to the pubic  
12 bone, so roughly -- however long that is.

13 Q. And the surgeon would then have to  
14 navigate through the abdominal cavity and work their  
15 way to place the mesh to repair the organ that was  
16 being prolapsed?

17 A. Correct, it was stated in a very colorful  
18 way, navigate through. Just go down there and get the  
19 job done, but, yes, you are right.

20 Q. And you don't mean to minimize the  
21 invasiveness of an open abdominal mesh repair of  
22 prolapse, are you, Doctor?

23 A. No. It's -- you know, there is an  
24 abdominal incision made, there are risks with that and

1 so I'm not going to say it's a minimally invasive  
2 nature compared to doing it robotically, no.

3 Q. The abdominal sacrocolpopexy performed  
4 with mesh has had a high success rate for vaginal vault  
5 prolapse, correct?

6 A. It would be arguably the best, yes.

7 Q. The use of polypropylene mesh in abdominal  
8 sacrocolpopexy was viewed as a advancement in the  
9 surgical treatment of pelvic organ prolapse, correct?

10 A. I think that's correct. The studies going  
11 back looking at cadaveric tissue found a higher failure  
12 rate with it. So polypropylene, through the abdominal  
13 route, has been shown with good and acceptable risk  
14 versus benefit ratio.

15 Q. The abdominal surgery for the placement of  
16 mesh can be a complicated surgery?

17 A. Well, I don't know what you mean by -- I  
18 mean, I do it routinely, overnight stay in the hospital  
19 and they're home. So complications can occur, I  
20 suppose.

21 Q. The open abdominal placement of mesh can  
22 be a surgery that lasts many hours?

23 A. Better not. I do it hour and 15 minutes,  
24 two days -- last Friday.



1 Q. Can it?

2 A. Well, not in my hands. I can't speak for  
3 other surgeons. I don't mess around.

4 Q. Do you agree that transabdominal surgery  
5 is associated with increased morbidity compared with  
6 vaginal repairs?

7 A. You have to define what you mean by  
8 vaginal repairs. Transvaginal nonmesh repairs  
9 traditionally have been associated with a lower  
10 morbidity, perioperative morbidity, but, again, it has  
11 to be balanced as far as with success, but now if you  
12 are talking about Prolift® meshes, that becomes a  
13 different story, which we'll get to later I'm sure.

14 So I think it's fair when you compare  
15 abdominal, transabdominal with an incision versus  
16 transvaginal without meshes, it's fair to say that the  
17 transvaginal without mesh would be a less morbid  
18 procedure.

19 Q. When you say "morbid" in that context,  
20 what do you mean?

21 A. Perioperative, intraoperative  
22 complications.

23 Q. Perioperative means during the procedure?

24 A. Perioperative -- well, perioperative means

1 just around the time of the surgery.

2 Q. And due to the morbidity of the open  
3 transabdominal procedure, many patients were unable to  
4 tolerate that procedure, correct?

5 A. Some patients wouldn't. I mean, my  
6 practice is not many, but some don't want to undergo  
7 that big of a surgery.

8 Q. So going back to this period in the 1990s  
9 and the early 2000s, researchers were reporting high --  
10 higher than desirable failure rates for nonmesh  
11 repairs, correct?

12 A. Done through the vagina.

13 Q. And there was a recognition that the use  
14 of mesh through the transabdominal route resulted in a  
15 more stable or durable repair, correct?

16 A. Correct.

17 Q. And there was some concern or desire to  
18 lower the morbidity of the transabdominal procedure,  
19 correct?

20 A. Correct.

21 Q. And so you agree, Doctor, it was a  
22 worthwhile research objective to investigate whether  
23 improvements could be made to the surgical devices and  
24 techniques for the treatment of pelvic organ prolapse,

1 correct?

2 A. I am an advocate of innovation so if  
3 there's a way of making something better, I am for it,  
4 but it has to be a safe advancement.

5 Q. So you agree that even today it's still a  
6 worthwhile research objective to find improved ways to  
7 surgically repair pelvic organ prolapse, correct?

8 A. Until we get to the day of 100% success  
9 and no complications, it's a worthwhile venture.

10 Q. Scientists, whether they're affiliated  
11 with universities or manufacturers or whatever, always  
12 are looking for ways to improve the surgical treatment  
13 of pelvic organ prolapse, correct?

14 A. I can't agree with that, no.

15 Q. Then let me rephrase.

16 The research into the improvements of the  
17 surgical techniques for pelvic organ prolapse has been  
18 going on several decades?

19 A. Yeah, longer than that, yes, I agree.

20 Q. Fair enough. You agree that it was  
21 admirable to search for a way to make pelvic organ  
22 prolapse recurrence -- withdrawn. Let me start over.

23 You agree it's admirable or it was admirable to  
24 search for a way to make the surgical repair of pelvic

1 organ prolapse result in fewer recurrences of the  
2 prolapse?

3 A. I feel it is a very worthwhile endeavor --  
4 if you want to use the word admirable that's okay -- to  
5 make a more efficacious and safe prolapse repair.

6 Q. Now, we've already discussed the  
7 hypothesis that polypropylene mesh might allow for a  
8 more stable or durable repair of the prolapse, correct?

9 A. Well, depends if you are talking about  
10 transabdominal or transvaginal.

11 Q. Well, the hypothesis that led to the use  
12 of mesh in transabdominal surgery as resulting in a  
13 more stable repair, that was actually borne out,  
14 correct?

15 A. That's true.

16 Q. And so you agree that that was a  
17 legitimate hypothesis?

18 A. Legitimate hypothesis?

19 Q. If you are having trouble with that word,  
20 I'll rephrase.

21 A. Yeah, let's -- can you use a different  
22 word?

23 Q. The research initiative that resulted in  
24 the use of mesh for the abdominal surgery to repair

1 pelvic organ prolapse, that turned out to be a  
2 worthwhile and useful innovation in the treatment of  
3 patients who have pelvic organ prolapse?

4 A. I think as we can state right now the use  
5 of transabdominal polypropylene meshes has improved the  
6 outcome as far as we know right now.

7 Q. There was another hypothesis that the use  
8 of a transvaginal mesh could cut down on the morbidity  
9 of the abdominal surgeries, correct, that was the idea  
10 at the time?

11 A. Well, the idea at the time was to blend  
12 meshes and avoid the potential issues of going through  
13 the abdomen, so that was their theory, but I can't  
14 speak to exactly what they were thinking. I wouldn't  
15 know.

16 Q. Let me just say it this way, Doctor, the  
17 reason and purpose behind the development of  
18 transvaginal mesh was to reduce the morbidity seen with  
19 the abdominal sacrocolpopexy approach, true?

20 A. That would be part of it.

21 Q. And you agree that that was a laudable  
22 goal, to search for a different way of doing the  
23 surgical procedure?

24 A. I will never criticize the pursuit of

1 innovation in improvement, as long as it's balanced and  
2 thought through.

3 Q. When the Prolift® was developed it was not  
4 the first time that surgeons implanted mesh  
5 transvaginally, correct?

6 A. No, mesh has been done -- not mesh, excuse  
7 me -- foreign body synthetics, manmade products have  
8 been used transvaginally at other times, yes.

9 Q. And even before the Prolene was developed,  
10 polypropylene mesh had been implanted transvaginally,  
11 correct?

12 A. Before the Prolift, yes, the Gynemesh® had  
13 been used, yes.

14 Q. And even before Gynemesh® transvaginal  
15 mesh was used in surgery for other applications,  
16 correct?

17 A. Well, you have to show me exactly what you  
18 are talking about. I mean, Marlex has been used, other  
19 products have been used, it had unacceptably high  
20 complication rates. I have to see exactly what product  
21 you are talking about.

22 Q. I'll rephrase.

23 Prior to the use of transvaginal mesh in pelvic  
24 organ prolapse, was transvaginal mesh used for

1 treatment of other conditions?

2 A. Transvaginal mesh for other conditions?

3 Oh, are we talking about like incontinence or something  
4 like that? I guess, yes, for incontinence.

5 Q. Before you were -- withdrawn.

6 Now, with respect to the Prolift® you're aware  
7 that there have been several randomized controlled  
8 clinical trials comparing the use of Prolift® to other  
9 surgical approaches, correct?

10 A. Yes, there have been quite a number of  
11 studies out there, yes.

12 Q. So I don't think this has been done yet  
13 for the benefit of the jury, but let's just explain  
14 what randomized controlled clinical trials are, okay?

15 A. Okay.

16 Q. So there's a variety of ways that  
17 scientists can undertake research, correct?

18 A. Yes.

19 Q. Sometimes you will have animal research,  
20 sometimes you have laboratory research and sometimes  
21 you have clinical research?

22 A. Correct.

23 Q. And one form of clinical research is what  
24 we call randomized controlled clinical trials?

1 A. That's correct.

2 Q. And in randomized controlled clinical  
3 trials you have two groups of patients that you try to  
4 have evenly matched?

5 A. Yes.

6 Q. And one group receives a treatment method  
7 and a different group either receives no treatment or  
8 sometimes a different treatment method?

9 A. Correct.

10 Q. And then the researchers follow those  
11 patients over time and see how they do both from a  
12 effectiveness perspective and a safety perspective?

13 A. Correct.

14 Q. And you would agree that randomized  
15 controlled clinical trials are some of the best quality  
16 research that can be done on a surgical procedure?

17 A. They can be if the study is run correctly,  
18 but they're one part of the information that's  
19 available.

20 Q. Now, there have been many randomized  
21 controlled studies done on the safety and effectiveness  
22 of Prolift®, correct?

23 A. Again, there have been studies done.  
24 There have been a number done.



1 Q. And there have been randomized controlled  
2 clinical studies done comparing the Prolift® to the  
3 older native tissue surgery, correct?

4 A. Correct.

5 Q. And that's something you looked at before  
6 you came to talk to the jury about your opinions on  
7 Prolift®, correct?

8 A. Correct.

9 Q. Some of those randomized controlled  
10 clinical trials looked to the relative success of the  
11 native tissue surgery compared to the Prolift® in  
12 repairing the woman's prolapse, correct?

13 A. As far as anatomical repairs, yes, that  
14 was looked at.

15 Q. And many of those high quality randomized  
16 controlled clinical studies demonstrated that women  
17 treated with a Prolift® experienced a lower rate of  
18 anatomical recurrence compared to the native tissue?

19 A. Well, again, you said "many". There are  
20 some that show anatomy success, there are also many  
21 that show equivocal results, but, again, anatomy is not  
22 what we look at.

23 Q. Well, Doctor, you're aware that there have  
24 been several studies done that -- and again we we're

1 talk -- withdrawn.

2 When we're talking anatomic success we're  
3 talking has the surgery been effective in returning the  
4 woman's internal organs to a more anatomically correct  
5 position?

6 A. That's what anatomical studies are about,  
7 but the woman doesn't care about that.

8 Q. And --

9 MR. ISMAIL: Move to strike as  
10 nonresponsive.

11 BY MR. ISMAIL:

12 Q. Can you answer the question I asked,  
13 Doctor?

14 A. I thought I did.

15 The anatomical studies look at the anatomy of  
16 the patient, not the psyche.

17 Q. Thank you.

18 And several randomized controlled clinical  
19 trials have demonstrated that Prolift® has a -- results  
20 in a better anatomical fix of the prolapse compared to  
21 the native tissue surgery, true?

22 A. Well, number one, I'd have to see those  
23 studies. Number two, we have to talk about which  
24 compartment they're talking about, anterior --

1 Q. I appreciate the distinction and I'll  
2 clarify.

3 When we talked about -- you've used the times  
4 anterior and posterior at times in your testimony?

5 A. Right.

6 Q. And just, again, because those aren't  
7 terms that laypeople often use, just to define them,  
8 anterior we're talking about, essentially, a bladder  
9 prolapse, correct?

10 A. Correct.

11 Q. And a posterior, we're talking about a  
12 rectal prolapse?

13 A. Correct.

14 Q. So let me focus on the anterior prolapse,  
15 okay.

16 Many randomized controlled clinical trials have  
17 demonstrated that surgery with a Prolift® results in a  
18 better anatomical repair of an anterior prolapse  
19 compared to a native tissue surgery, true?

20 A. Well, I'd have to somewhat disagree.  
21 There are going to be some studies out there that show  
22 better anatomy, but I have to look at those specific  
23 studies, but they also show equivocal. So, again, how  
24 do you want to define many? You know, say 100, five,

1 one? So I just have to see.

2 Q. Okay. How many are you aware of?

3 A. I have reviewed 450 manuscripts, I can't,  
4 off the top of my head, come up with them.

5 Q. Certainly, Doctor, you wouldn't dispute  
6 that Prolift® has been shown to result in a better  
7 anatomical repair of an anterior prolapse compared to a  
8 native tissue surgery?

9 A. You know, I've never really argued against  
10 anatomic repair, that's not an issue for me, it's the  
11 patient's quality of life is. So an anterior, you can  
12 find studies that show better or equivocal in anatomic  
13 repair. Posterior and apical, it's a different story.

14 Q. Agree that nobody -- you agree that  
15 nobody, including you, would dispute anatomic success  
16 with mesh is very strong?

17 A. I would agree with you that it has been  
18 shown to work, again, but that's not the issue that I'm  
19 concerned about in our patients.

20 Q. Thus far, Doctor, we've been talking about  
21 anatomic success of the surgery and you, as you just  
22 did, want to make reference to another measure of  
23 success and that is symptomatic --

24 A. Correct.

1 Q. -- outcomes, correct?

2 A. You are correct.

3 Q. Symptomatic outcomes have been measured as  
4 well in some of these studies that we've discussed,  
5 correct?

6 A. Correct.

7 Q. Including in some randomized controlled  
8 clinical trials, correct?

9 A. Correct.

10 Q. Patients with a Prolift® surgery have  
11 demonstrated improvement in symptomatic results,  
12 correct?

13 A. Yes, that has happened, yes.

14 Q. Patients implanted with a Prolift® have  
15 demonstrated improvements in quality of life, correct?

16 A. That has been demonstrated, yes.

17 Q. You referenced earlier biologic or cadaver  
18 tissue being used in pelvic organ prolapse; is that  
19 right?

20 A. Correct.

21 Q. Surgical experience with those techniques  
22 revealed the biological or cadaver tissue in  
23 sacrocolpopexy had a high failure rate?

24 A. With specifically sacrocolpopexy it --

1 several different studies have shown it was not as  
2 strong.

3 Q. So the biologic tissues that you  
4 referenced in your testimony are not as strong as the  
5 polypropylene mesh for repair, right?

6 A. Well, we're talking about transabdominal.  
7 Transabdominal I agree with you.

8 Q. Now, there were other polypropylene  
9 transvaginal mesh kits developed other than the  
10 Prolift®, correct?

11 A. That is correct.

12 Q. Developed by different manufacturers?

13 A. Correct.

14 Q. What are some of the other manufacturers  
15 who have developed polypropylene transvaginal mesh kits  
16 for prolapse repair?

17 A. Coloplast, AMS, Bard, Boston Scientific,  
18 and there may be some more in there. Those are the  
19 ones I see the most.

20 Q. And do you believe, Doctor, you have done  
21 a comprehensive review of the scientific literature on  
22 the randomized controlled trials involving transvaginal  
23 mesh for all these products?

24 A. I reviewed the PubMed, which is the

1 world's largest search engine, 24 million articles I  
2 recall, and I have reviewed -- you know, it's as  
3 comprehensive as I'm going to be able to get.

4 Q. Can you confirm, Doctor, that the Prolift®  
5 has been studied in more randomized controlled clinical  
6 trials than any other transvaginal mesh used in  
7 prolapse repair?

8 A. I don't doubt that, no.

9 Q. Doctor, you made some comments earlier  
10 about the amount of clinical trials that had been done  
11 on the Prolift® at various points in time; do you  
12 recall that in your testimony?

13 A. I don't recall that.

14 Q. You don't?

15 A. I'm sure I've been asked that question,  
16 yes.

17 Q. One of the procedures that you described  
18 that you are aware of at your institution is the  
19 robotic abdominal sacrocolpopexy?

20 A. Correct.

21 Q. Now, at the time that you participated in  
22 that surgery, when you first started doing that  
23 surgery, you were not aware of any randomized  
24 controlled trial anywhere in the world, correct?

1           A.    I and my colleague were the first in the  
2 world to do it, so there's no way of having a  
3 randomized controlled trial.

4           Q.    And even today there is not a randomized  
5 controlled clinical trial on the use of robotic  
6 abdominal sacrocolpopexy for the treatment of prolapse,  
7 correct?

8           A.    No, there's been laparoscopic versus  
9 robotic, I have reviewed those papers, those papers are  
10 out there.

11          Q.    When did those come out?

12          A.    Oh, those came out years ago.

13          Q.    When?

14          A.    I reviewed -- I have no idea. I reviewed  
15 them, they asked me to review it because of my  
16 expertise so there are going to be those trials out  
17 there. I don't -- right now as I sit here can't think  
18 of one robotic versus open.

19          Q.    Let me -- by the way, with respect to the  
20 robotic procedure you just described, you don't operate  
21 the robot in that procedure?

22          A.    No, my colleague does.

23          Q.    See how we're doing on time, Doctor.

24          Now, with respect to this robotic abdominal



1     sacrocolpopexy procedure that you participate in, do  
2     you use polypropylene mesh?

3             A.     Yes.

4             Q.     And you continue to use mesh in that  
5     procedure, correct?

6             A.     For that specific procedure, yes.

7             Q.     And you have for the last ten years?

8             A.     Longer than that. Probably 2003 with the  
9     robotically and then prior to that was transabdominal.

10            Q.     The mesh that you use in your practice is  
11     called InterPro?

12            A.     InterPro by AMS.

13            Q.     The InterPro mesh that you use in your  
14     practice you believe is a large pore mesh, correct?

15            A.     No.

16            Q.     Do you believe the InterPro mesh that you  
17     use in your clinical practice is a lightweight mesh?

18            A.     No. It would probably be -- I would have  
19     to look up the specific numbers, it would probably be a  
20     moderate weight. I don't recall the exact numbers.  
21     They're quite similar to Gynemesh®.

22                   MR. ISMAIL: I'm going to mark this as  
23                   Exhibit 1 and we'll remark it for trial  
24                   purposes later.

1 (Document marked for identification as  
2 Deposition Exhibit No. 1.)

3 BY MR. ISMAIL:

4 Q. First of all, Doctor, you indicated in  
5 your last answer that the mesh you use in your clinical  
6 practice is a polypropylene mesh that's very similar to  
7 the mesh that's used in the Prolift®, correct?

8 A. I didn't say very similar. I said it's  
9 similar to.

10 Q. Okay. I will rephrase.

11 You agree, Doctor, that the mesh you use in  
12 your clinical practice is a mesh that's very --  
13 withdrawn.

14 The mesh you use in your clinical practice is  
15 similar to the polypropylene mesh used in the Prolift®,  
16 correct?

17 A. Correct.

18 Q. I've handed you what we've marked for  
19 identification as Exhibit 1.

20 Is this an article that you are listed as an  
21 author on?

22 A. That's correct.

23 Q. And it is on the use of robotic  
24 sacrocolpopexy in prolapse repair?

1 A. That is correct.

2 Q. And in this article, Doctor, do you tell  
3 the medical community what materials you use in the  
4 procedure?

5 A. Yes, we do.

6 Q. And do you describe the polypropylene mesh  
7 that you use in your procedure?

8 A. Yes.

9 Q. If you turn to Page 2 of the article, in  
10 the left column.

11 A. Yes.

12 Q. And in there you inform the medical  
13 community on the technique for this robotic procedure  
14 that you are describing in the article, right?

15 A. That is correct, yes.

16 Q. And if you work your way down in that left  
17 column, above the anatomical cartoon there, you make  
18 specific reference to the polypropylene mesh that you  
19 use in your procedure, right?

20 A. That is correct.

21 Q. Do you say, quote, Next, a Y-shaped large  
22 pore, lightweight polypropylene graft (InterPro;  
23 American Medical Systems) is sutured into the vagina?

24 A. That's what we state, yes.

1 Q. So you, in your article that you published  
2 to the medical community, describe InterPro as a large  
3 pore lightweight polypropylene mesh, correct?

4 A. That is correct.

5 Q. The date of this article, sir, was -- is  
6 what?

7 A. 2015.

8 Q. In fact, it was submitted and received by  
9 the journal on May 26, 2015, correct?

10 A. That's correct.

11 Q. That's some -- that's several years after  
12 you had begun work already on behalf of the plaintiff  
13 lawyers in this case?

14 A. That is correct.

15 Q. It's after you formed your opinions about  
16 Gynemesh®, correct?

17 A. That's correct.

18 Q. So when you published for the medical  
19 community -- withdrawn.

20 You published in the medical community that  
21 InterPro, the mesh you use, is large pore, right?

22 A. That's correct.

23 Q. You talked about pore size with Mr. Slater  
24 several times earlier today, correct?

1 A. Correct.

2 Q. You agree that the porosity of the mesh  
3 used in Prolift® is similar to InterPro, correct?

4 A. Well, Prolift® is only a transvaginal  
5 procedure. So transvaginal versus transabdominal,  
6 we're talking different procedures there.

7 MR. ISMAIL: Move to strike as  
8 nonresponsive.

9 BY MR. ISMAIL:

10 Q. Do you remember my question, Doctor?

11 A. No, I do not.

12 Q. I'll restate it.

13 The polypropylene mesh you use, InterPro, has a  
14 porosity similar to Gynemesh®?

15 A. That is correct.

16 Q. The porosity of Gynemesh® is similar to  
17 the mesh used in the Prolift® kit, correct?

18 A. Should be the same.

19 Q. So the answer to that is yes?

20 A. Yes.

21 Q. And you described your -- the mesh you use  
22 as large pore, correct?

23 A. That is correct.

24 Q. You also described the mesh you use as

1 lightweight, correct?

2 A. Correct.

3 Q. The mesh -- the polypropylene mesh you use  
4 is -- has a similar weight to the Gynemesh®, correct?

5 A. That is correct.

6 Q. And the Gynemesh® would have a similar  
7 weight to that used -- the mesh used in the Prolift®  
8 kit, correct?

9 A. That's correct.

10 Q. By the way, Doctor, do you know whether  
11 the mesh you use in your practice has bi-directional  
12 elasticity?

13 A. It doesn't.

14 Q. It does not?

15 A. No.

16 Q. So the missing characteristic of  
17 bi-directional elasticity hasn't stopped you from using  
18 InterPro mesh in your practice, right?

19 MR. SLATER: Objection, lack of  
20 foundation, mischaracterization of direct.

21 THE WITNESS: Because I'm using it through  
22 an abdominal route, just like Gynemesh® is  
23 still available for abdominal route, so you  
24 can't compare the two surgeries.

1 BY MR. ISMAIL:

2 Q. I haven't compared anything, Doctor. My  
3 question was different. Do you remember it or do you  
4 want me to restate it?

5 A. Please restate it.

6 Q. The missing characteristic of  
7 bi-directional elasticity has not stopped you from  
8 using InterPro mesh in your procedures, correct?

9 MR. SLATER: Objection,  
10 mischaracterization and lack of foundation.

11 BY MR. ISMAIL:

12 Q. You can answer the question.

13 A. Yeah, I can't give you -- I think it would  
14 be unfair to give you a yes or no. I have to say I'm  
15 doing it through a different route.

16 If I were doing it through the vagina,  
17 absolutely. Through the abdomen I have not seen that  
18 issue.

19 MR. ISMAIL: Move to strike as  
20 nonresponsive.

21 BY MR. ISMAIL:

22 Q. Again, it's not -- I have not compared it  
23 to transvaginal surgery or not. It's a very simple  
24 question, Doctor.

1           A.    And I feel I need to explain it to be  
2 accurate.

3                   MR. ISMAIL:   Move to strike as  
4 nonresponsive.

5 BY MR. ISMAIL:

6           Q.    Do you have my question in mind?

7           A.    No, I still do.

8           Q.    Well, let me restate it, just for the  
9 benefit of the record.

10           The mesh that you use in your clinical practice  
11 you believe does not have bi-directional elasticity,  
12 correct?

13           A.    Correct.

14           Q.    And that has not stopped you from using  
15 that mesh in your abdominal sacrocolpopexy procedure,  
16 correct?

17           A.    As you are specifically stating there, you  
18 are correct, through the abdomen, I agree with you.

19                   MR. ISMAIL:   Okay.   When did we start,  
20 12:40.   Everyone doing okay?

21                   THE WITNESS:   Can I get something to  
22 drink?

23                   MR. SLATER:   Take five minutes.

24                   MR. ISMAIL:   Sure.



1 THE WITNESS: I can get something. I'm  
2 out of fluid here.

3 THE VIDEOGRAPHER: The time is 1:47 and we  
4 are off the record.

5 (Brief recess.)

6 THE VIDEOGRAPHER: The time is 1:53. And  
7 we are back on the record.

8 BY MR. ISMAIL:

9 Q. Doctor, I want to turn now to something in  
10 your prior testimony regarding the instructions for use  
11 that you offered.

12 Now, prior to being retained by the plaintiff  
13 lawyers, you had never before looked at a  
14 manufacturer's internal standards for what to include  
15 in the instructions for use, correct?

16 A. That is correct.

17 Q. And if we were to consider your articles  
18 that you've published in the literature, you've never  
19 before published on the standards that a manufacturer  
20 uses for instruction for use, correct?

21 A. Correct.

22 Q. With respect to the Prolift® instructions  
23 for use, before you got involved in this case you had  
24 never even read the Prolift® instruction for use,

1 correct?

2 A. Well, again, I know I did not read the  
3 Gynemesh®, I know that, but I visited the booth at  
4 Ethicon and, as I recall, looked at the IFU, looking at  
5 it online. I can't recall specific dates.

6 Q. One moment, Doctor.

7 MR. SLATER: If you are going to pull a  
8 transcript or something just let me know so I  
9 can look for it. Is it the Bellew transcript  
10 or something else?

11 MR. ISMAIL: This will be the witness'  
12 deposition. I have a copy for you if you'd  
13 like.

14 MR. SPECTER: That would be great. Thank  
15 you.

16 MR. SLATER: Yeah, sure. Splendid.

17 MR. ISMAIL: I'll give one to you too in a  
18 minute, Doctor.

19 Doctor -- ready to proceed everyone? I'll  
20 give you page and line when we get there.  
21 Adam.

22 MR. SLATER: What's that?

23 MR. ISMAIL: Ready to proceed?

24 MR. SLATER: Oh, yeah. I figured you

1                   would tell us the page and line before you --

2                   MR. ISMAIL: I will.

3 BY MR. ISMAIL:

4                   Q. Doctor, you referenced earlier you gave a  
5 deposition in this case, correct?

6                   A. Correct.

7                   Q. And when you gave that deposition you took  
8 an oath to tell the truth, correct?

9                   A. That's correct.

10                  Q. Same type of oath that you took today?

11                  A. Correct.

12                  Q. And you understood when you took that oath  
13 that it was as if you were in court?

14                  A. Correct.

15                  Q. There was a court reporter there who was  
16 taking down the questions that were asked and the  
17 answers that you gave, correct?

18                  A. Correct.

19                  Q. I ask, Doctor, if you turn to Page 391 of  
20 your deposition?

21                  MR. SLATER: Just one thing for the

22 record, I just -- I'm looking what you asked,

23 just -- well, actually, I'll withdraw it. You

24 go ahead. What page did you say?

1 MR. ISMAIL: 391, Line 1.

2 BY MR. ISMAIL:

3 Q. Doctor, were you asked this question:

4 "Before becoming engaged in this litigation,  
5 had you ever reviewed the Prolift® instructions for  
6 use?"

7 Is that the question you were asked?

8 A. Before I -- you're on Line 9?

9 Q. Line 1.

10 A. Oh, Line 1. I'm sorry.

11 Q. Let me begin again.

12 A. I'm sorry.

13 Q. Doctor, were you asked this question and  
14 did you give this answer:

15 "Question: Before becoming engaged in this  
16 litigation, had you ever reviewed the Prolift®  
17 instructions for use?

18 Answer: No, I had not."

19 Was that your sworn testimony, sir?

20 A. That's what I gave then, yes.

21 Q. Before being involved in this litigation  
22 had you ever read the instruction for use for  
23 Gynemesh®?

24 A. Gynemesh®, I don't recall ever reading

1     that, no.

2                 Q.     So when you discussed earlier that you had  
3     used instructions for use in your interaction with  
4     residents, do you recall giving testimony to that  
5     effect?

6                 A.     Yes.

7                 Q.     That was a more general statement  
8     regarding how using instructions for use in other  
9     contexts besides the Prolift®, correct?

10                A.     Correct.

11                Q.     So you never taught or interacted with  
12     residents before this litigation on the Prolift®  
13     instruction for use, correct?

14                A.     I think that would be fair. We looked it  
15     up online, what was available, but it was not a formal  
16     teaching. It was more of an idea of what happens with  
17     the procedure.

18                Q.     Now, you're not suggesting, Doctor, that  
19     the instruction for use is the only way surgeons obtain  
20     information about the surgeries they perform, are you?

21                A.     It is not the only way. It is one of the  
22     ways.

23                Q.     Surgeons obtain information pertinent to  
24     surgery from numerous sources, right?

1 A. Possibly. It depends upon the surgeon.

2 Q. So surgeons obtain information relevant to  
3 surgery from their own education, right?

4 A. Well, I can't speak for all surgeons out  
5 there. Everybody is different. There are different  
6 levels of surgeons and different levels of motivation  
7 and different levels of quality delivered, so I can't  
8 speak for everybody.

9 For me, at an institution I am in and the  
10 ability to travel all over the world for meetings, the  
11 IFU takes less of a meaning. If I'm out in the middle  
12 of USA somewhere, they become more important. So,  
13 again, I can't speak for everybody.

14 Q. Let me rephrase.

15 You are aware, Doctor, that surgeons can rely  
16 on their education and training to understand the risks  
17 and benefits of surgeries that they perform?

18 A. They can, yes.

19 Q. Surgeons can rely on the medical  
20 literature to understand the risks and benefits of the  
21 surgeries they perform?

22 A. That is another avenue for it, yes.

23 Q. Surgeons can look to medical conferences  
24 as another source of information about the risks and

1     benefits of surgeries they perform, correct?

2             A.     Possibly, if they're able to go to the  
3     meetings, yes.

4             Q.     Surgeons can rely on their own clinical  
5     experience when understanding the risk and benefits of  
6     the surgeries they perform, correct?

7             A.     Possibly, if they performed the procedure  
8     before.

9             Q.     Surgeons -- have you ever heard --  
10    withdrawn.

11            Have you ever heard of a surgical guide?

12            A.     Yes.

13            Q.     Surgical guides have been prepared in  
14    addition to instructions for use, correct?

15            A.     That's a generic statement for everything,  
16    but there are surgical guides available for some  
17    procedures.

18            Q.     And surgeons can look to a surgical guide  
19    or a monograph to learn information about the risks and  
20    benefits of a surgery they can perform?

21            A.     If that's available, they can do that,  
22    yes.

23            Q.     When you were on direct examination with  
24    Mr. Slater you did not discuss the surgical guides or

1 monographs with Prolift®, correct?

2 MR. SLATER: Objection.

3 THE WITNESS: I wasn't asked.

4 BY MR. ISMAIL:

5 Q. So the answer to my question is correct?

6 A. Yes, you are correct.

7 Q. Mr. Slater asked you some questions about  
8 design standards; do you recall that?

9 A. Correct.

10 MR. SLATER: Objection,  
11 mischaracterization.

12 BY MR. ISMAIL:

13 Q. Prior to being retained by the plaintiff  
14 lawyers in this case had you ever been aware of the  
15 internal design standards that a manufacturer uses to  
16 develop a new surgical device?

17 A. Specifically that? I mean, I have patents  
18 of my own on a product, was involved in the early  
19 stages of designing of a product as a resident, but as  
20 you narrow it down there are specific industry  
21 standards, my level of knowledge would be not as much  
22 as it is now.

23 Q. When you say "not as much as it is now,"  
24 you mean through your work as a paid witness on behalf



1 of the plaintiffs, right?

2 A. Yes and no to that. It's through my work,  
3 yes, definitely through the litigation, but also as my  
4 internal curiosities, what are the standards industry  
5 is required to do, because I'm a surgeon implanting  
6 devices and I kind of want to know what really goes on  
7 behind the scenes.

8 Q. Okay. So if we focus on the period of  
9 time as of when you were first retained by the  
10 plaintiff lawyers, you would agree that you did not  
11 have experience with the internal design standards a  
12 manufacturer uses to develop a new surgical device,  
13 correct?

14 A. Well, no, if you look at my CV, I was  
15 involved in transurethral enzymatic ablation of the  
16 prostate, which I worked with a researcher and the  
17 founder of the company and working with the FDA as far  
18 as getting it approved, that's when I was a resident.

19 I worked with the design of a new artificially  
20 designed urinary sphincter for males by Timm, T-i-m-m  
21 is the name of him, so we were working on the standards  
22 with the companies, and then my own patent. And so it  
23 depends how extensive a level of knowledge.

24 I'm not an FDA -- I'm not employed by the FDA.

1 I didn't design any FDA regulations but I have working  
2 knowledge of what would be required.

3 Q. Let me rephrase my question. And I'm  
4 talking about internal --

5 MR. SLATER: Can I -- I'm sorry, I just  
6 got a text and I have to call somebody back  
7 really quick. I don't want to -- if it's a bad  
8 spot, I just -- it has nothing to do with work.

9 MR. ISMAIL: Off the record.

10 MR. SLATER: Thanks.

11 MR. ISMAIL: Sure.

12 THE VIDEOGRAPHER: The time is 2:03 and we  
13 are off the record.

14 (Brief recess.)

15 THE VIDEOGRAPHER: The time is 2:07 and we  
16 are back on the record.

17 BY MR. ISMAIL:

18 Q. Doctor, let me rephrase my prior question  
19 to make it more specific.

20 Prior to being retained by the plaintiff  
21 lawyers in this litigation you had no experience on the  
22 internal design standards a manufacturer uses for the  
23 development of a new surgical device for treatment of  
24 pelvic organ prolapse, correct?

1           A.     I don't know. I would have to say that is  
2     only partially correct. As I mentioned previously, as  
3     far as my experience designing, as far as the  
4     transenzymatic ablation of the prostate, which was  
5     going through the FDA, we had FDA people come in,  
6     working in with them, the -- an artificially made  
7     sphincter for male incontinence with Dr. Timm, working  
8     and designing to the point of implanting in humans.  
9     And then with my patent, working with it. So those are  
10    all looking at safety, complications, ramifications.

11                   MR. ISMAIL: Move to strike as  
12                   nonresponsive.

13   BY MR. ISMAIL:

14           Q.     Doctor, I'm not intending to ask anything  
15    about the FDA in my question, okay?

16           A.     Okay.

17           Q.     And you agree you are not an FDA expert,  
18    right?

19           A.     I know what the standards they are going  
20    after, but I have not been employed by the FDA.

21           Q.     So my question is very specific. I would  
22    ask that you only answer that question.

23                   Prior to being retained by the plaintiffs in  
24    this litigation, you did not have experience on the

1 internal design standards a company used to develop a  
2 new surgical device for pelvic organ prolapse, true?

3 A. Correct, I have never been an employee of  
4 any industry designing those issues.

5 Q. You earlier referenced, Doctor, the  
6 results of the TVM group in France; do you recall that,  
7 in the early development work on the Prolift®?

8 A. Yeah, we discussed two or three earlier  
9 studies.

10 Q. And you used the clinical study report in  
11 reference to the results of their success rate in the  
12 surgical use of the Prolift®, correct?

13 A. That is correct. As long as we're  
14 talking, it was Plaintiff Exhibit P0049, I assume we're  
15 talking about that one.

16 Q. Yes. And there were two arms to the TVM  
17 study, correct, one in Europe and one in the United  
18 States?

19 A. Oh, yes, yes. I'm sorry, I misunderstood,  
20 yes.

21 Q. And the data that you went over with  
22 Mr. Slater only related to the European TVM data?

23 A. That is correct, yes, not the American.

24 Q. Doctor, do you agree that pelvic organ

1 prolapse surgeries -- withdrawn.

2 I think you told us earlier that all surgeries  
3 have risks associated with them, correct?

4 A. Well, all surgeries have their unique  
5 complications of it, severity, frequency, but surgeries  
6 can have some complications. Again, we have to define  
7 what surgery we're talking about.

8 Q. All right. Let's break it down.

9 All surgeries have sort of general risks  
10 related to surgery; anesthesia, potential infection,  
11 any time you are cutting tissue there is a potential  
12 risk, right?

13 A. Again, if you are talking about -- I'm not  
14 trying to be difficult, but I don't want to make a  
15 general statement. If we're talking about a skin  
16 biopsy in a dermatologist's office is different than  
17 cardiac surgery. So, again, that's why -- as a surgeon  
18 I have to define what I'm talking about, what  
19 procedure.

20 Q. Then we'll be specific.

21 With any pelvic organ prolapse surgery, even in  
22 the hands of the most skilled surgeon, there can be  
23 complications, correct?

24 A. Each surgery has its own unique

1 complications, frequency and ability to treat those  
2 complications.

3 Q. And even yourself, Doctor, you would never  
4 guarantee a patient that a surgery you performed will  
5 be free of complications, correct?

6 A. You are correct.

7 Q. With any surgery in -- for pelvic  
8 reconstruction you have potential problems with  
9 bleeding, right?

10 A. It can happen. Certain procedures have  
11 higher risk, others have lower risk, but it can happen.

12 Q. Any surgery for pelvic reconstruction has  
13 risks associated with the use of anesthesia, correct?

14 A. Yeah, unless you are using a local  
15 anesthetic for biopsy, yeah, but, again, I don't like  
16 making a general statement. A procedure takes three  
17 hours versus one that takes ten minutes, there's  
18 different risks so everything is -- again, I don't want  
19 to be difficult by any means, but I'm a surgeon so we  
20 look at each specific procedure.

21 Q. The potential surgeries that could be used  
22 for repair of pelvic organ prolapse all carry a  
23 potential risk of infection, correct?

24 A. It depends. If you are using a foreign

1 product, foreign body, the risk goes up. If you are  
2 not, I have -- I have, in my experience, never had a  
3 transvaginal procedure using native repair get  
4 infected.

5 Q. Do you have the -- I guess this is a  
6 different. Sorry, forgot to give you the other day but  
7 feel free to hold on to that. Not to add to your  
8 paper, Doctor, but here you go.

9 Doctor, I've handed you a transcript of  
10 testimony you gave on March 4, 2015; is that correct?

11 A. March -- you gave me March 3rd and  
12 March 4.

13 Q. I would like you to focus on March 4,  
14 please.

15 A. Okay.

16 Q. And you swore to tell the truth in that  
17 deposition, correct?

18 A. That is correct.

19 Q. I'm going to ask you to turn to Page 513  
20 of your testimony.

21 A. Okay, I'm there.

22 Q. Line 21. Was this your question -- it was  
23 a question asked of you and was this your answer under  
24 oath:

1 "And with any surgery, no matter what it is,  
2 you've got problems of -- potential problems with  
3 bleeding or infection or anesthesia problems, and so  
4 forth; correct?

5 Answer: In a general sense, yes."

6 Were you asked that question and did you give  
7 that answer under oath?

8 A. Yeah, and I agree with that answer still.

9 Q. And once you go on to the specific surgery  
10 at issue, there are potential complications with each  
11 specific surgery, correct?

12 A. Each surgery has its own unique  
13 complications.

14 Q. And that's true with surgeries in the  
15 pelvic floor, correct.

16 A. That is correct.

17 Q. There is a potential of serious injury  
18 with sacrocolpopexy, correct?

19 A. Well, it depends on when you are talking  
20 about injury to what? Again, that's not to be  
21 difficult but injury to the heart? No. Injury to the  
22 organs --

23 Q. To the patient?

24 A. To the patient in general, there is the



1 potential for -- yeah, there is potential risk there.

2 Q. There is a potential risk of serious  
3 injury to the patient with a colporrhaphy procedure?

4 A. Not in my experience there hasn't been,  
5 but, I mean, again, I need to know what kind of  
6 complication you are talking about. I think we need to  
7 be clear.

8 Q. Doctor, I ask that you turn to transcript  
9 that I gave you earlier of your deposition taken on  
10 November 16th.

11 MR. SLATER: Objection.

12 BY MR. ISMAIL:

13 Q. First transcript I gave you, Doctor.

14 A. I have it, yes.

15 Q. Page 244.

16 A. 344?

17 Q. 244.

18 A. I don't have a 2 -- mine starts at 200  
19 something.

20 Q. I'll give you that.

21 MR. SLATER: Stingy with the transcripts.

22 MR. ISMAIL: There you go.

23 MR. SLATER: That's what I heard about  
24 you.

1 THE WITNESS: 244.

2 BY MR. ISMAIL:

3 Q. Yes, sir.

4 A. 244, I'm there.

5 Q. All right, Doctor. This, again, was sworn  
6 testimony you gave and the date of this was  
7 November 16, 2012; is that correct?

8 A. Correct.

9 Q. I'm sorry, 243, Doctor.

10 A. Okay. I'm there.

11 Q. Line 11.

12 "Question: Would you agree that there's a  
13 potential risk of serious --

14 Sorry, Line 7.

15 "Would you agree that there is a potential risk  
16 of serious injury with the sacrocolpopexy?

17 Answer: Yes."

18 Is that the question you were asked and answer  
19 you had given?

20 A. Yes, and I agree with that.

21 Q. Were you also asked is there "... a  
22 potential risk of serious injury with the sacrospinous  
23 ligament fixation?"

24 Your answer, "In a magnitude and frequency and

1 intensity and delayed onset difference but, yes,  
2 there's a risk."

3 And then you were asked at Line 19:

4 "Would you agree that there's a potential risk  
5 of serious injury with a sacrospinous ligament  
6 fixation?

7 Answer: There is -- there is a risk there for  
8 serious injury, yes."

9 Were you asked that question and were you  
10 giving that answer under oath?

11 A. Yes, and I agree with that.

12 Q. And then on Page 244, what I really  
13 intended to direct you to in the first place, Line 2,  
14 would you agree that there's a serious risk with  
15 colporrhaphy?

16 What was your answer under oath?

17 A. "Yes."

18 Q. There are risks with hysterectomies,  
19 correct, Doctor?

20 A. Yes.

21 Q. All prolapse surgeries have -- carry the  
22 risk to other organs, correct?

23 A. Again, yes. We have to define what organ  
24 but --

1 Q. Right, I'm not talking about the heart.  
2 I'm talking about the organs near the surgery that  
3 you're performing.

4 A. Correct, that -- that is an inherent risk  
5 with operating in that region, yes.

6 Q. There is an inherent risk of operating in  
7 that region of injuries to the nerves of the patient,  
8 correct?

9 A. Well, it depends what nerves you are  
10 talking about and it depends what prolapse surgery,  
11 that's why sacrospinous fixation I was very specific  
12 on, okay, or semi-specific.

13 The risks of sacrospinous fixation are comp --  
14 significantly different than abdominal sacrocolpopexy  
15 or more significant than anterior colporrhaphy.

16 So, again, as far as nerve injury, it depends  
17 what nerves that we're talking about.

18 Q. Page 89 of the November 15, 2012  
19 testimony.

20 A. Okay. I'm there.

21 Q. Line 21, were you asked this question:  
22 "All prolapse surgeries have a risk to nerves?"  
23 What was your sworn answer, Doctor?

24 A. You know, yeah, I see that, I say --

1 Q. My question is what was your sworn answer,  
2 Doctor?

3 A. "Yes."

4 Q. Thank you.

5 All prolapse surgeries have a risk of pain,  
6 correct?

7 A. Again, I'd have to define the severity,  
8 the frequency, et cetera, but pain, to a certain  
9 degree, is a risk of all prolapse surgeries.

10 Q. That's inherent to the surgery, right?

11 A. That's inherent to that specific surgery,  
12 correct.

13 Q. All prolapse surgeries have a potential  
14 risk of pain with sexual intercourse, correct?

15 A. Yes. Again, as I'll state over and over,  
16 it depends upon the severity, the frequency, the  
17 progressive nature, but, yes, dyspareunia, pain with  
18 intercourse, can't happen with all of them, but they  
19 might not all have the severity of the pain.

20 Q. Page 90 of your testimony, Doctor, Line 2:  
21 "Question: All prolapse surgeries have a  
22 potential risk of dyspareunia; correct?"

23 What was your answer, sir? Line 4.

24 A. Yeah, yes, I state it that there, as I've

1 clarified today.

2 Q. All prolapse surgeries have a potential  
3 risk of pelvic pain, correct?

4 A. Again, dependent upon the procedure and  
5 the severity, they can be different, but they can all  
6 have pain, but, again, it depends upon that specific  
7 procedure.

8 Q. Line 5 of Page 90 of your testimony:

9 "Question: All prolapse surgeries have a  
10 potential risk of pelvic pain; correct?"

11 What was your sworn answer under oath, sir?

12 A. "Yes," with the clarifier I just did.

13 Q. In fact, persistent pain is a complication  
14 of prolapse surgeries other than the Prolift®, correct?

15 A. Again, that depends upon the severity and  
16 frequency. There's clarifiers.

17 Q. Turn to page -- of the November 16  
18 testimony, Doctor. Line 21.

19 A. What page?

20 Q. I'm sorry. 454.

21 A. 454, Line 21, okay, I'm there.

22 Q. "Question: Persistent pain is a potential  
23 complication with other prolapse surgeries besides  
24 Prolift®, correct?"

1           What was your sworn testimony under oath, sir?

2           A.    Yeah, as I said --

3           Q.    What was your testimony, sir?

4           A.    I agree with that statement, yes, with the  
5 clarifiers I added today.

6           Q.    You didn't add those clarifiers at the  
7 time when you were giving your sworn testimony, true?

8           A.    I did not, no, you are correct.

9           Q.    As a surgeon any time you perform a  
10 prolapse surgery, re-operation is a potential risk  
11 going into the surgery, correct?

12          A.    That is correct, yes.

13          Q.    And just like you've never guaranteed a  
14 patient that a surgery will be complication-free,  
15 you've never guaranteed a patient that a surgery  
16 necessarily will be effective, correct?

17          A.    Effective as far as treating the symptoms  
18 and the anatomical occurrence, I agree with you, yes.

19          Q.    There can be re-operation because of a  
20 failure of the prolapse surgery in doing its intended  
21 job of fixing the prolapsing problem, correct?

22          A.    That is a risk, yes.

23          Q.    And that's inherent to all prolapse  
24 surgeries, correct?

1           A.    I don't know of any procedure that is 100%  
2 perfect.

3           Q.    There could also be a need for  
4 re-operation to -- because a complication has occurred,  
5 that necessitates some surgical intervention, correct?

6           A.    Well, again, re-operation can occur, but,  
7 again, we have to look at what type of complication it  
8 is, how severe it is and can we fix it, but, yes, in a  
9 general sense, I agree with you.

10          Q.    And that's inherent to all prolapse repair  
11 surgeries, correct?

12          A.    Yes, as I mentioned with all those  
13 different qualifiers on there.

14          Q.    You testified this morning about the term  
15 mesh exposure; do you recall?

16          A.    Yes.

17          Q.    And you indicated that sometimes the  
18 terminology in this area can get -- get confusing  
19 because folks use different terms to describe different  
20 things?

21          A.    That is correct.

22          Q.    And so whenever you're reviewing any  
23 document that talks about complications for mesh  
24 surgery, you want to make sure you understand whether



1 the author -- what the author means by a mesh exposure  
2 versus mesh erosion, et cetera?

3 A. That is correct, including the term  
4 palpable.

5 Q. Mesh exposure is a well known risk of any  
6 surgery involving mesh, correct?

7 A. That is true.

8 Q. Whether the mesh is placed transvaginally  
9 or transabdominally, correct?

10 A. Correct. Again, there is going to be  
11 differences in frequency and severity, but, yes.

12 Q. And so when we're talking about mesh  
13 exposure we're talking about when the implanted mesh  
14 becomes visible or palpable?

15 A. In the vagina, correct, not in the bladder  
16 or another organ, that's different.

17 Q. Correct.

18 And that's called a mesh erosion, right?

19 A. It should be called that but there will be  
20 different terms, that's why it gets confusing for  
21 everybody.

22 Q. So that goes back to how we started this  
23 part of our discussion, the terms exposure and erosion  
24 sometimes are used interchangeably, but, in your view,

1     there's a clear distinction between them?

2             A.     Correct.  You would have to look, when  
3     going through medical records, of what the doctor is  
4     actually really describing, what they actually saw.

5             Q.     The amount of mesh exposed can be small,  
6     correct?

7             A.     It can be, yes.

8             Q.     Mesh exposure actually can be  
9     asymptomatic, right?

10            A.     It can be, yes.

11            Q.     When we say "asymptomatic," that means the  
12    patient is not experiencing any symptoms from the mesh  
13    exposure, correct?

14            A.     That is correct, yes.

15            Q.     When dealing with a mesh exposure the  
16    physician can try conservative measures to treat it,  
17    right?

18            A.     That is one of the options, yes.

19            Q.     And you certainly advocate conservative  
20    methods to treat a mesh exposure, correct?

21            A.     It depends on the severity of the mesh  
22    exposure.  If it's large, highly symptomatic, then, no.  
23    If it's small, asymptomatic, then, yes, as initial  
24    treatment.

1 Q. Okay. I appreciate the clarification but  
2 just so it's clear, a doctor should consider, in the  
3 first instance, whether conservative treatment of a  
4 mesh exposure is warranted or whether something more  
5 invasive would be appropriate; is that fair to say?

6 A. That is correct, yes.

7 Q. Now, with regard to the Prolift®, you  
8 agree that approximately 50% of mesh exposures can be  
9 treated conservatively?

10 A. That is, I'd say, old data. If you look  
11 at Abbott, et.al., no, they disagree with that, but of  
12 those 50% treated conservatively, 50% of those went on  
13 to surgery. So the old data, yes, but not the new  
14 data.

15 MR. ISMAIL: Move to strike as  
16 nonresponsive.

17 BY MR. ISMAIL:

18 Q. If you have your November 15 --

19 A. 2012, yeah, because that's old.

20 Q. All right. Well, let me make sure we're  
21 clear.

22 A. Sure.

23 Q. At the time you gave your sworn testimony  
24 in this case you agreed that approximately 50% of mesh

1 exposures can be treated conservatively, true?

2 MR. SPECTER: Counsel -- pardon me,  
3 counsel. I object. When you say "in this  
4 case" are you talking about the Hammons case or  
5 the transvaginal mesh litigation generally?

6 MR. ISMAIL: I will rephrase.

7 MR. SPECTER: Thank you.

8 BY MR. ISMAIL:

9 Q. At the time of your November 2012  
10 deposition did you agree, Doctor, that approximately  
11 50% of mesh exposures can be treated conservatively?

12 A. Yes, I agree with you specifically in  
13 2012, but that's what I'm saying, new data has come out  
14 to say that I was incorrect at that time.

15 MR. ISMAIL: Move to strike as  
16 nonresponsive and hearsay everything after  
17 "yes."

18 BY MR. ISMAIL:

19 Q. The conservative ways of treating a mesh  
20 exposure with Prolift® would include just watching and  
21 observing the patient to see how she is doing?

22 A. It has to be a case by case situation.

23 Q. We've described that conservative  
24 treatment of a mesh exposure is sometimes available for

1 a physician and patient, correct?

2 A. Correct.

3 Q. And I'm trying to define for the jury what  
4 that means when we say "conservative treatment," okay?

5 A. Okay.

6 Q. When we say conservative treatment of a  
7 mesh exposure, what we're saying is the physician and  
8 patient can do nothing but observation to see if the  
9 problem improves, correct?

10 A. That is a treatment option based upon a  
11 case by case situation. You have to evaluate all the  
12 variables.

13 Q. And sometimes a conservative treatment  
14 option would include use of a topical estrogen cream,  
15 correct?

16 A. That is one of the options, yes.

17 Q. Less conservative treatment would include  
18 excising the exposed mesh, correct?

19 A. That is correct.

20 Q. The -- if a -- withdrawn.

21 Sometimes an excision of exposed mesh can be  
22 done in a ten or 15 minute procedure, correct?

23 A. I can't speak to that. I have not done  
24 that.

1           Q.    You're aware, Doctor, that some exposed  
2    meshes that have gone on to excision can be done in a  
3    ten or 15 minute procedure?

4           A.    I don't doubt that it can be done.    The  
5    question is how effective it is.

6           Q.    Now, this other term that you used,  
7    erosion, that was a term that you used with Mr. Slater  
8    this morning, correct?

9           A.    That is correct.

10          Q.    And you've defined a mesh erosion to mean  
11   when the mesh enters an adjacent organ, correct?

12          A.    Correct, that would be the current  
13   terminology.

14          Q.    And that's different than a vaginal  
15   exposure of mesh, correct?

16          A.    That is correct, yes, but we have to be  
17   careful on who is doing the defining on medical records  
18   and things, but, yeah.

19          Q.    Mesh erosion is a well-known risk of any  
20   mesh surgery using -- withdrawn.

21          Mesh erosion is a well-known risk of any mesh  
22   surgery, correct?

23          A.    Yeah, but, again, it's going to depend  
24   upon which -- you are talking anti-incontinence

1 procedure, prolapse, transabdominal, robotic. There is  
2 going to be different risks, severity of the risk of  
3 frequency, but, yes, I agree with you.

4 Q. You mentioned urinary dysfunction this  
5 morning in some of your answers to Mr. Slater; do you  
6 recall that?

7 A. Yes, I do.

8 Q. Urinary dysfunction can be a complication  
9 of numerous prolapse surgeries other than with a  
10 Prolift®, correct?

11 A. Again, as I've mentioned, severity,  
12 frequency, ability to treat it is going to be  
13 different, but it can occur.

14 Q. In fact, a woman can have voiding  
15 dysfunction just from a prolapse in her bladder,  
16 correct?

17 A. That can occur. It's relatively rare,  
18 but, yes, it can occur.

19 MR. ISMAIL: Mr. Slater, during the course  
20 of my examination we have sought clarification  
21 for the agreement that you say exists regarding  
22 payments to witnesses and the feedback that  
23 we've gotten -- that I've gotten is that my  
24 line of question is perfectly appropriate.

1 MR. SLATER: Who did you speak to? You  
2 want to do this on the record?

3 MR. ISMAIL: Do I want to -- say what now?

4 MR. SLATER: Do you want to have this  
5 conversation on the record?

6 MR. ISMAIL: I'm telling you that I'm --

7 MR. SLATER: Who did you talk to?

8 MR. ISMAIL: We've been doing it by  
9 e-mail.

10 MR. SLATER: With who?

11 MR. ISMAIL: With the -- I think you  
12 called them national folks.

13 MR. SLATER: No, the national folks  
14 weren't in the room when it was made so --

15 MR. ISMAIL: Well, who -- okay, then  
16 perhaps.

17 MR. SLATER: It was during the deposition  
18 of Dr. Weber, the Tucker Ellis lawyers.

19 MR. ISMAIL: That what?

20 MR. SLATER: Look, I don't know what  
21 they're telling you so --

22 MR. ISMAIL: Wait a minute.

23 MR. SLATER: That was what was agreed and  
24 look at what they questioned Dr. Weber on, look



1 at the questioning in the other depositions.

2 MR. ISMAIL: Wait. So you are saying that  
3 in our examination of Dr. Weber we agreed not  
4 to ask Dr. Weber --

5 MR. SLATER: Total amount she was paid  
6 outside the case, yes. She was only asked  
7 about what she was paid in this case.

8 MR. ISMAIL: And the agreement was inn  
9 exchange for what?

10 MR. SLATER: We would do the same with  
11 your experts.

12 MR. ISMAIL: But did you ask our experts  
13 about how much they were paid.

14 MR. SLATER: I didn't.

15 Yeah, in this case.

16 MR. ISMAIL: No, no, in other cases.

17 MR. TOMASELLI: Ms. Baldwin.

18 MR. SLATER: Well, I don't know what to  
19 tell you about that. Someone should have  
20 objected, but, you know, I can just tell you  
21 that --

22 MR. ISMAIL: Okay. So --

23 MR. SLATER: I don't know why you are  
24 shaking your head. This is the agreement. If

1 she asked a question like that, maybe someone  
2 in the room could have said to her, hey, did  
3 you forget about the deal? And then she -- if  
4 she forgot she would have said okay, but I'm  
5 not going to change, okay.

6 Dr. Elliott didn't prepare to talk about  
7 total amounts he was paid and that's not what  
8 we're going to get into today. That was the  
9 agreement in this litigation. In the  
10 conversations I was in and with the experts I'm  
11 handling, that's how it's been done. If  
12 Ms. Baldwin went beyond because she forgot,  
13 someone on your side should have been awake and  
14 said, hey, we have an agreement, and I'm sure  
15 she would have said, oh, I forgot.

16 MR. ISMAIL: Or that's not the agreement.

17 MR. SLATER: I think that it clearly was.  
18 Did you look at Dr. Weber's transcript?

19 MR. ISMAIL: I actually have had a chance  
20 to read Dr. Weber's transcript.

21 MR. SLATER: Did you see what she was  
22 asked about?

23 MR. ISMAIL: I know what she was asked  
24 about. Whether Dr. Weber was asked or not does

1 not make it an agreement.

2 MR. SLATER: Was it placed on the record,  
3 on the transcript or was it just agreed with me  
4 and Mr. Moriarity and he's not telling you what  
5 we talked about? I mean, you think he didn't  
6 ask her about what she's been paid in total  
7 because he didn't feel like it?

8 MR. ISMAIL: So I'm just --

9 MR. SLATER: I know for a fact we made  
10 this agreement.

11 MR. ISMAIL: Okay.

12 MR. SLATER: So I'm not going to change my  
13 position because when I make a deal with  
14 somebody, I abide by it and I expect them too  
15 also and not send two new lawyers in to pretend  
16 they didn't know about it.

17 MR. ISMAIL: Okay. We have --  
18 Mr. Moriarity is one of the lawyers with whom  
19 we checked.

20 MR. SLATER: He is the one I reached the  
21 deal with so I will be happy to speak to him  
22 directly.

23 MR. ISMAIL: Terrific. So my reference  
24 to --

1 MR. SLATER: Want to take a break and put  
2 him on the telephone?

3 MR. ISMAIL: Jesus, can I actually finish  
4 my statement?

5 MR. SLATER: I don't know, can you?

6 MR. ISMAIL: You keep interrupting me.

7 MR. SLATER: Sorry.

8 MR. ISMAIL: So our understanding of what  
9 you describe as a deal regarding expert  
10 payments and bias is different. Your  
11 colleagues in this litigation have not acted as  
12 if there is an agreement to that issue. You  
13 have asked and your team has asked those  
14 questions so we don't think your standing on  
15 some blanket objection to covering this with  
16 Dr. Elliott is appropriate and to the extent  
17 you are correct and some time down the line the  
18 Court agrees with you, then that won't get  
19 played, but we're all here on a Saturday to  
20 accommodate Dr. Elliott's schedule --

21 MR. SLATER: We're not doing it.

22 MR. ISMAIL: -- and the appropriate thing  
23 to do is to let him answer the question so that  
24 we don't have to reconvene testimony of

1 Dr. Elliott to get what would be bias  
2 information because you don't want to do it  
3 now, and if you're right, then it doesn't get  
4 played to the jury so you are not prejudiced.

5 MR. SLATER: We're not doing it. In fact,  
6 if you talk to national counsel in the MDL you  
7 will find that is the agreement throughout the  
8 national litigation on both sides.

9 Have you spoken to them?

10 MR. ISMAIL: Who is the national counsel  
11 in the MDL?

12 MR. SLATER: Butler Snow.

13 MR. ISMAIL: Yeah, we've checked with them  
14 too.

15 MR. SLATER: And there's -- in the MDL  
16 people are not limiting it to the amount you  
17 were paid in that case?

18 Judge Goodman ruled that when a witness  
19 testifies in these trials it's not to be asked  
20 about.

21 MR. ISMAIL: I understand, but the rules  
22 in Pennsylvania are different.

23 MR. SPECTER: Actually, counsel, the rules  
24 in Pennsylvania are informed by Maughan versus

1 Hahnemann, which I suggest you read.

2 MR. ISMAIL: I did check the rules on  
3 whether bias can be -- and whether a witness  
4 has been -- has received a significant amount  
5 of income testifying on behalf of a certain  
6 side, that information is relevant and goes to  
7 the jury.

8 So I'm offering these observations and  
9 inviting you to do the sensible thing here and  
10 let the witness answer and we can fuss later  
11 what gets played to the jury. If we're right,  
12 it gets played; if you're right, it doesn't get  
13 played.

14 MR. SLATER: We abide by our agreements,  
15 nor do we fabricate different agreements.

16 MR. ISMAIL: Okay.

17 MR. SLATER: I once heard someone say  
18 that.

19 MR. ISMAIL: So for the purposes of  
20 preserving my record, you're going to instruct  
21 Dr. Elliott to refuse to answer any questions  
22 about the amount of money he has been paid,  
23 other than the time relating to Ms. Hammons,  
24 correct?

1 MR. SLATER: Exactly, because that's the  
2 agreement we have in this litigation.

3 MR. ISMAIL: All right. And so no matter  
4 how I phrase the question as to the amount of  
5 money that Dr. Elliott has been paid by the  
6 plaintiffs to testify against Ethicon in  
7 particular or other manufacturers, you are  
8 going to instruct him not to answer, correct?

9 MR. SLATER: If you ask him beyond  
10 Hammons, he's not going to answer.

11 MR. ISMAIL: When did he begin working on  
12 Hammons, so I know how to phrase the question?

13 MR. SLATER: I have no idea. Why don't  
14 you ask him?

15 MR. ISMAIL: Well, I don't think he knows  
16 either.

17 As of what date are you going to let him  
18 answer the question?

19 MR. SLATER: Why don't you ask him "how  
20 much money have you been paid in this case to  
21 your knowledge," and he will do his best to  
22 answer the question.

23 MR. SPECTER: You are talking about the  
24 Hammons case, Adam?

1 MR. SLATER: Yeah, in the Hammons case.

2 MR. ISMAIL: I suspect we're going on --  
3 never mind. Okay. We can go back on the  
4 record.

5 THE VIDEOGRAPHER: Never off.

6 MR. ISMAIL: We have been on the record  
7 this whole time?

8 THE VIDEOGRAPHER: Yes.

9 MR. ISMAIL: Excellent. Glad all that was  
10 on the record.

11 BY MR. ISMAIL:

12 Q. Okay. Now we can go back with the  
13 questioning, Doctor.

14 Among the specific risks that are well known  
15 with any pelvic floor surgery is the risk of  
16 dyspareunia following the surgery, correct?

17 A. Again, as I've mentioned, the severity,  
18 frequency and ability to treat is going to be different  
19 between the procedures, but there is a known risk with  
20 each procedure.

21 Q. During your fellowship you were aware that  
22 there was a risk of dyspareunia with prolapse surgeries  
23 you were being trained on, correct?

24 A. Again, as I mentioned, severity and



1 frequency and ability to treat is going to be different  
2 between each procedure.

3 Q. So the answer to that is yes?

4 A. Well, again, I have to -- I can't just  
5 give a yes or no because it's dependent upon each  
6 specific procedure. Sacrospinous ligament fixation is  
7 different than uterosacral, it's different than  
8 anterior colporrhaphy and posterior colporrhaphy.

9 Q. So let's focus on the colporrhaphy  
10 procedure. Those are the native tissue surgeries  
11 that -- some of the older surgeries that were used to  
12 treat a prolapse, correct?

13 A. Correct.

14 Q. You were aware -- withdrawn.

15 You acknowledge that women with -- who have  
16 anterior colporrhaphy can suffer from pain with sexual  
17 intercourse after they've had the surgery, correct?

18 A. Again, with the issue of the severity,  
19 frequency and ability to treat it, yes.

20 Q. During your residency you were aware that  
21 there was a potential risk of painful sexual  
22 intercourse with colporrhaphy surgeries, correct?

23 A. I don't know. We're going back a long  
24 time there. I didn't learn much in residency on

1 prolapse, that's why I did a fellowship.

2 Q. All right.

3 A. So I can't speak with accuracy of what I  
4 knew then. Fellowship is a different story.

5 Q. Let me rephrase my question so -- to make  
6 it easier for you.

7 During your medical training you were aware  
8 that there was a potential risk of dyspareunia, painful  
9 intercourse with colporrhaphy surgeries, true?

10 A. Again, I was aware of that issue  
11 occurring, but, again, the severity, frequency and  
12 ability to treat it is going to be different, but, yes.

13 Q. When it comes to posterior colporrhaphy  
14 the risk of painful sexual intercourse is actually  
15 higher than with the anterior repair, correct?

16 A. You can have papers saying both ways as  
17 far as higher and lower, depending upon are you doing a  
18 spot repair, are you doing a standard plication, are  
19 you using -- so, again, if you compare anterior versus  
20 posterior, posterior is going to have a potentially  
21 higher risk.

22 Q. Now, there are many factors that can lead  
23 to dyspareunia, correct?

24 A. Multifactorial is a correct answer, yes.

1           Q.    There are many different things that have  
2   to be and should be considered when evaluating a woman  
3   for dyspareunia, correct?

4           A.    Multiple factors should be considered,  
5   yes, that's true.

6           Q.    We talked earlier about the fact that  
7   women can have dyspareunia from a prolapse itself,  
8   correct?

9           A.    That can happen.  It's going to be a  
10   different type of dyspareunia but dyspareunia, again,  
11   it's a generic term.  We're talking if they have a  
12   major vault prolapse, they are going to have a  
13   different level of discomfort than a sacrospinous  
14   fixation or more specific prolapse.

15          Q.    Vaginal atrophy can lead to dyspareunia,  
16   correct?

17          A.    Yeah, and usually it's treatable or  
18   reducible.

19          Q.    One of the -- and just so we explain to  
20   the jury what we mean by vaginal atrophy, one of the  
21   things that can occur as a result of menopause is that  
22   the woman doesn't make as much estrogen following  
23   menopause, correct?

24          A.    Correct.

1 Q. And the decline or decrease in estrogen  
2 can lead to vaginal atrophy, correct?

3 A. Correct.

4 Q. And vaginal atrophy is something that is  
5 associated with menopause, correct?

6 A. Correct.

7 Q. And vaginal atrophy is a condition that  
8 women have that can progress or get worse as women age,  
9 correct?

10 A. If left untreated, yes.

11 Q. A vaginal hysterectomy carries the risk of  
12 dyspareunia, correct?

13 A. Yeah. Again, it depends upon the  
14 condition being treated. If it's a uterine prolapse,  
15 dyspareunia goes -- or is reduced. If it's for some  
16 other reason, it could be increased. So, again, we  
17 have to look at the specifics.

18 Q. I just want to make sure you have my  
19 question in mind because I'm not sure -- it seemed like  
20 you are answering a different question.

21 The question is, Doctor, a vaginal hysterectomy  
22 carries the risk of dyspareunia, true?

23 A. Yeah, I was being -- I was being more  
24 specific as the cause, the etiology of the prolapse.

1 If you just took a generic hysterectomy, can  
2 dyspareunia be associated with that? To some extent  
3 the answer to that is yes.

4 Q. Now, let me ask it this way: You would  
5 agree that there's a background rate of women who have  
6 dyspareunia who have never had any prolapse surgery,  
7 correct?

8 A. That is correct, there is a given  
9 percentage that probably increases with age, but,  
10 again, we don't know the severity of that and ability  
11 to treat it.

12 Q. The question of whether dyspareunia is  
13 associated with prolapse surgery, is something that has  
14 been evaluated in randomized controlled clinical  
15 trials, correct?

16 A. Off the top of my head I can't think of  
17 the study that has looked at that, but, yeah, I mean,  
18 that is a very -- or it should be a very common thing  
19 to look at.

20 Q. You are aware, Doctor, for your work in  
21 this litigation that randomized controlled clinical  
22 trials have considered whether patients who are  
23 surgically -- had prolapse surgically repaired develop  
24 dyspareunia, correct?

1 MR. SLATER: Objection.

2 THE WITNESS: Correct, I would want to  
3 look at those specific studies because you have  
4 to look at how they are framed, but there are  
5 studies out there. I think Lowman, et.al.  
6 perhaps is the name. There's going to be  
7 others.

8 BY MR. ISMAIL:

9 Q. I'm not referring to a specific article  
10 now, Doctor, I'm just asking whether you are aware, as  
11 part of your work in this case, that randomized  
12 controlled clinical trials, some of them, have looked  
13 at whether a patient who had a surgical repair of  
14 prolapse developed dyspareunia?

15 MR. SLATER: Objection to this, vague  
16 types of questioning. Subject to tie up, you  
17 can answer it.

18 THE WITNESS: You know, looking at the  
19 totality of studies out there, yeah, there are  
20 studies out there which dyspareunia is a  
21 component what they look at. If you are  
22 looking at one specifically on dyspareunia and  
23 long term, those are going to be fewer.

24 BY MR. ISMAIL:

1           Q.    You're aware that there are randomized  
2   controlled clinical studies that have compared the  
3   development of dyspareunia following surgery with a  
4   group of patients who have had a Prolift® and a group  
5   of patients who had native tissue repair?

6           A.    Those studies have been done, yes.

7           Q.    And what those studies allow you to do is  
8   see whether -- which group of patients developed  
9   dyspareunia and at what rates, correct?

10          A.    Yes and no. During that study period,  
11   yes, but it doesn't say anything beyond that.

12          Q.    Then let me rephrase.

13                One of the things that randomized controlled  
14   clinical studies can do in this context that we've been  
15   discussing is see, for example, whether during the  
16   study period more patients who had the native tissue  
17   surgery developed dyspareunia compared to the Prolift®,  
18   correct?

19          A.    Yes, as you phrased it there, during the  
20   study period, I agree with you.

21          Q.    And you are familiar that those kinds of  
22   studies have been done comparing Prolift® to native  
23   tissue surgery, true?

24          A.    There have been several studies out there

1 along those lines, yeah.

2 Q. Certain randomized controlled clinical  
3 studies have also assessed whether patients reported an  
4 improvement in sexual function following prolapse  
5 surgery, correct?

6 A. Again, I'd want to see the specific study  
7 we're referring to.

8 Q. I'm just asking about your awareness of  
9 the body of scientific information when you came to  
10 testify today.

11 A. I'm aware of many studies looking at many  
12 things, but each study has to be analyzed very  
13 specifically.

14 Q. I'm just asking generally, Doctor, whether  
15 you're aware whether there are randomized controlled  
16 clinical studies that have examined whether women have  
17 reported improvements in sexual function following  
18 prolapse surgery?

19 A. Yeah, there are studies out there that  
20 looked at sexual function following surgery, whether  
21 they improve or are worsened.

22 Q. And you're aware, Doctor, that certain  
23 women report improvement in sexual function following  
24 surgery with a Prolift®, right?



1           A.    Yeah.  Again, we have -- I need to see  
2    specifics, but in a very general sense that has been  
3    reported during that study period.  I can't speak to  
4    afterwards though.

5           Q.    You earlier, Doctor, read some portion  
6    of -- withdrawn.

7           You made some -- withdrawn.

8           As you come here today having considered the  
9    information that you've described for us earlier with  
10   respect to the Prolift® or the Gynemesh® you have not  
11   seen any study that has shown a dyspareunia rate of 60%  
12   in women using the Prolift®, true?

13          A.    60%?  I mean, I'm not going to be --

14          Q.    That's the number you used earlier in your  
15   testimony which is why I asked.

16               MR. SLATER:  Objection,  
17   mischaracterization and foundation.

18               THE WITNESS:  Yeah, I'd have to see what I  
19   said.  I don't know what we're -- it's been a  
20   long day so I don't recall those specifics.  
21   I'd have to see what I said.

22   BY MR. ISMAIL:

23          Q.    Then let's clarify.

24          As you sit here now, Doctor, you are not trying

1 to suggest to the jury that there are studies that  
2 report a 60% dyspareunia rate with Prolift®, are you?

3 A. I'm not prepared -- without looking at the  
4 literature, I can't say one way or the other it was  
5 60%, no.

6 Q. I want to make -- I think we had a double  
7 negative in there.

8 You agree, as you sit here today, you are not  
9 suggesting to the jury that there are studies reporting  
10 a 60% dyspareunia rate with Prolift®, true?

11 A. Yeah, right now as I sit here, I can't  
12 recall that study.

13 Q. And, Doctor, you're aware of randomized  
14 controlled clinical studies that have shown during the  
15 study period that Prolift® has no higher rate of  
16 dyspareunia compared to native tissue surgery, true?

17 A. Well, again --

18 MR. SLATER: Objection.

19 MR. SPECTER: Pardon me, counsel.

20 MR. SLATER: Objection.

21 MR. SPECTER: Let me just interpose an  
22 objection if I may, counsel. You have several  
23 times now made reference to literature without  
24 showing it to the witness, without asking if

1           it's authoritative. That can't be evaluated by  
2           the witness or by opposing counsel so I object  
3           to all those questions, including that past  
4           one, for that reason.

5           MR. SLATER: That was part of my objection  
6           previously too, when I asked about tie up  
7           because I don't think it's appropriate.

8           MR. ISMAIL: Well, first of all, I'm not  
9           sure who is objecting and who isn't anymore  
10          but --

11          MR. SPECTER: We both were.

12          MR. ISMAIL: Clearly.

13 BY MR. ISMAIL:

14           Q. Doctor, here is my question and if you  
15           tell me you don't know, then you tell me you don't  
16           know.

17           Are you aware of randomized controlled clinical  
18           trials that have shown that for the study period  
19           Prolift® was not associated with an increased risk of  
20           dyspareunia?

21           MR. SLATER: Objection, same reasons  
22           previously stated and --

23           THE WITNESS: Again --

24           MR. SLATER: And one second -- and we're

1 going to move to strike all these questions at  
2 the appropriate time because they're  
3 inappropriate.

4 THE WITNESS: Again, this is very  
5 frustrating for me because I need to see these  
6 papers and whenever I bring up a paper's name,  
7 you move to strike it and so now when you are  
8 asking, I ask for the paper and so I can't see  
9 it. So I need to look at the paper, the  
10 quality of the paper and let's discuss each  
11 paper.

12 MR. ISMAIL: Move to strike as  
13 nonresponsive.

14 BY MR. ISMAIL:

15 Q. You can't answer my question, Doctor?

16 A. I just did. I can't -- you are correct,  
17 as you are phrasing it, I can't. I want to see those  
18 papers.

19 Q. All right. Do you have your testimony  
20 that you gave on March 4, 2015, sir?

21 A. Yes, I do.

22 Q. Page 539, Line 24.

23 A. 539.

24 Q. Yes, sir.

1 A. 539, Line 4. I'm there.

2 Q. Sorry, Line 23.

3 A. Oh, I'm sorry. 23, yes.

4 Q. "Question: And as reported in the  
5 studies, am I correct that there has been no difference  
6 or no showing among the studies we've talked about to  
7 suggest that Prolift® has a higher rate of dyspareunia  
8 than the native tissue?

9 Answer: I agree with -- as you stated that  
10 question, I agree with the caveat as I mentioned  
11 before."

12 And then you were asked to answer that question  
13 yes or no.

14 And at Line 13 you said, I agree with you as  
15 stated, yes.

16 Is that your sworn testimony?

17 A. That's what I state there. I don't know  
18 what studies we're referring to.

19 Q. So you can put that aside, Doctor, and let  
20 me ask it this way: without reference to the testimony,  
21 do you now recall, Doctor, that there are randomized  
22 controlled clinical trials that have demonstrated for  
23 the study period that Prolift® is not associated with  
24 an increased rate of dyspareunia compared to native

1 tissue surgeries?

2 A. Again, I was very specific with that  
3 testimony and being consistent, you know, there are a  
4 lot of clarifiers you have on there. During the study  
5 period, randomized control, I would want to see those  
6 studies. We can talk about each one individually, but  
7 that's what I stated on March 4. I stand by that.

8 Q. My question is different, Doctor. I'm not  
9 asking with regard to the testimony. I'm asking about  
10 your recollection now.

11 A. Okay.

12 Q. My ques -- my purpose was to refresh your  
13 recollection, okay?

14 A. Okay.

15 Q. So here's my question: Do you recall, as  
16 you sit here today, that there are randomized  
17 controlled clinical studies that have shown for the  
18 study period that Prolift® is not associated with an  
19 increased risk of dyspareunia compared to native  
20 tissues?

21 MR. SLATER: Objection, it's the same  
22 objection. And I just want to say one other  
23 thing, I've looked at the testimony now, your  
24 foundation is -- it's a mischaracterization and

1           lack of foundation for this line of questioning  
2           about RCTs versus the testimony you read. You  
3           should look at the line of questioning. It's  
4           not based on an RCT, but go ahead.

5           MR. ISMAIL: So I will restate my question  
6           so you have it in mind.

7           THE WITNESS: Well, no --

8           MR. ISMAIL: No, I will and to address  
9           Mr. Slater, I have the option of refreshing the  
10          witness' recollection without showing the  
11          testimony and that's what this question is,  
12          okay?

13          MR. SLATER: Without showing the  
14          testimony?

15          MR. ISMAIL: Yes, on the screen to the  
16          jury, that's what refreshing recollection is.  
17          You don't publish it to the jury. So which  
18          I --

19          MR. SLATER: No, I'm just telling you that  
20          what you did was, in my opinion, inappropriate  
21          and a mischaracterization of what actually was  
22          going on there.

23          MR. ISMAIL: I got your question -- I got  
24          your objection, so here's my question.

1 BY MR. ISMAIL:

2 Q. Doctor, without reference to the  
3 testimony, let me start over, okay. You can put it  
4 aside.

5 As you sit here today, sir, do you have a  
6 recollection that there are randomized controlled  
7 clinical studies that have shown for the study period  
8 that Prolift® is not associated with an increased  
9 increase of dyspareunia compared to native tissue  
10 surgeries?

11 A. Okay. With my hands being somewhat tied,  
12 because I can't look at these studies, I do have a  
13 recollection of there being studies, in the short term,  
14 that can show it being equivocal or not statistically  
15 different between Prolift® and the native repairs.

16 Q. Okay. And when you say "not statistically  
17 different" in your last answer, just so that the jury  
18 is clear, researchers perform a statistical  
19 significance test often when doing clinical research,  
20 correct?

21 MR. SLATER: Objection,  
22 mischaracterization, lack of foundation.

23 THE WITNESS: Correct.

24 BY MR. ISMAIL:



1 Q. And when we talk about statistical  
2 significance in clinical research, that is a process by  
3 which you say is the observation we're looking at  
4 potentially by chance or is it -- you know, fairly  
5 represent what the outcomes with the treatment being  
6 offered, correct?

7 A. Correct, if it's by chance or if it's a  
8 real finding.

9 Q. And your last answer was -- withdrawn.  
10 One second. Let's break for one minute.

11 THE VIDEOGRAPHER: Off the record. 2:52  
12 and we are off the record.

13 (Brief recess.)

14 THE VIDEOGRAPHER: The time is 3:16 and we  
15 are back on the record.

16 BY MR. SLATER:

17 Q. Dr. Elliott, you were just asked some  
18 questions about whether or not one can attribute  
19 complications to a Prolift® where a woman has issues  
20 after a Prolift® surgery, do you remember you were  
21 asked about that by defense counsel a while back?

22 A. Yes.

23 Q. If a patient as a mesh erosion, are you  
24 able to say, just knowing that, that the Prolift® is a

1 factor in that complication?

2 MR. ISMAIL: Objection, incomplete  
3 hypothetical.

4 THE WITNESS: Yes.

5 BY MR. SLATER:

6 Q. And why is that?

7 A. Without mesh there would be no erosion.

8 Q. If a patient has mesh contraction and that  
9 is causing symptoms, are you able to say that the mesh  
10 and the Prolift® itself is a part of a factor in  
11 causing that complication?

12 A. Yes, without mesh there's no contraction.

13 Q. During the questioning by defense counsel  
14 you were asked several questions about the risks of the  
15 Prolift® through the vagina versus the other types of  
16 surgery, for example, abdominal sacrocolpopexy, and I  
17 think you were trying to draw some distinctions. I'd  
18 like to give you an opportunity now to explain what the  
19 distinctions are in terms of the various complications  
20 or issues that can arise from these different  
21 surgeries?

22 A. Okay. Just in general?

23 Q. Sure.

24 MR. ISMAIL: Objection to the narrative.

1                   THE WITNESS: You have to look at the --  
2                   what is done during the two procedures, Number  
3                   one, abdominal versus going through the vagina,  
4                   so the risk of contamination of the mesh is  
5                   going to be different. You have to look at the  
6                   shape of the mesh.

7                   There are no arms for sacrocolpopexy, not  
8                   going through any muscles, so you can't have  
9                   that contraction pulling on muscles.

10                  You can get the mesh to lay flat because,  
11                  again, it's not being pulled like we talked  
12                  about earlier with the mesh arms.

13                  The volume of mesh is significantly  
14                  different, like when we showed -- when I picked  
15                  up the mesh. In general, those are the  
16                  specifics.

17       BY MR. SLATER:

18                  Q. You were asked by defense counsel if there  
19                  are some patients who have had some improvements in  
20                  their quality of life and you acknowledged, yes, some  
21                  patients have had improvement with the Prolift®.

22                  Do you remember that?

23                  A. Yes.

24                  Q. Have there been patients who have had

1 complications with the Prolift®?

2 A. Oh, yes, yeah.

3 Q. Have there been patients who have had  
4 severe life-changing complications with the Prolift®?

5 A. Yeah.

6 MR. ISMAIL: Objection, lack of  
7 foundation, repeating direct.

8 THE WITNESS: Devastating complications.

9 BY MR. SLATER:

10 Q. You were asked multiple questions about  
11 suture surgeries and suture repairs.

12 Do suture surgeries have mesh-related risks?

13 A. No.

14 Q. You were asked a question a few minutes  
15 ago and I think counsel said something about older  
16 procedures that were used to treat prolapse and he  
17 mentioned colporrhaphy I think a few minutes ago.

18 Is colporrhaphy done today?

19 A. It's the most common procedure done today.

20 Q. So it's not an older procedure in the  
21 sense that it's something people used to do but don't  
22 do anymore; is that fair?

23 A. No, it's considered what we say is the  
24 traditional surgery, been done for many years and will

1 continue to be done.

2 Q. Is anybody performing Prolifts® today?

3 MR. ISMAIL: Objection, 403, subsequent  
4 remedial measure.

5 THE WITNESS: No.

6 BY MR. SLATER:

7 Q. You were asked about studies, RCTs in  
8 particular that study dyspareunia.

9 Are you familiar with the fact that in the  
10 Altman RCT they found a 7% de novo dyspareunia rate  
11 with the Prolift® and only 2% with colporrhaphy?

12 MR. ISMAIL: Objection, hearsay, leading.

13 THE WITNESS: That's what they state in  
14 the report, yes.

15 BY MR. SLATER:

16 Q. You were asked if there were some women  
17 who report improvement in sexual function after the  
18 Prolift®?

19 A. Correct.

20 Q. Are there some women who report quite  
21 different results with their sexual function after the  
22 Prolift®?

23 A. Yes.

24 Q. For example?

1           A.     Worsening, devastated or gone, that's what  
2     I see in my clinic.

3                     MR. ISMAIL:   Objection, move to strike.

4     BY MR. SLATER:

5           Q.     Doctor, do you have handy the transcript  
6     that counsel asked you about from March 4, 2015?

7           A.     Yes, I have it right here.

8           Q.     What I'm going to do is go back and look  
9     at it a little bit and let's see what you were actually  
10    asked about at that time.  And if you look at Page 536,  
11    Line 9, the article that was identified --

12          A.     I'm sorry.  I'm sorry, let me just get  
13    there.

14          Q.     Sure.  Page 436, Line 9, the article that  
15    was identified is the Lowman article?

16          A.     That is correct.

17          Q.     You know that study, you are familiar with  
18    that?

19          A.     Yes.

20                     MR. ISMAIL:   Objection, hearsay.

21                     MR. SLATER:   I'm sorry, didn't you  
22    question him about it, sir?

23                     MR. ISMAIL:   No, I didn't question him  
24    about 536.  I was his own transcript and asking

1           him a question about it, and said here's a  
2           statement of him.

3   BY MR. SLATER:

4           Q.   If you read forward, and you can scan  
5   forward from Page 536 where it was identified and if  
6   you get to this testimony you were actually asked about  
7   by defense counsel, Page 539, Page 540, that's all  
8   asking about the Lowman article, correct?

9           A.   Yes, that is all the Lowman article.

10          Q.   All right. Well, we happen to have that  
11   here --

12               MR. ISMAIL:  Objection, hearsay.

13               MR. SLATER:  And here it is, PLT302.  Here  
14   you go, counsel.

15               MR. ISMAIL:  Thank you.

16   BY MR. SLATER:

17           Q.   And I'm just going to try to do this  
18   fairly quickly.  This is the published article where  
19   they in the results say there was a de novo rate of  
20   dyspareunia of 16.7%.

21               You see that?

22               MR. ISMAIL:  Objection, hearsay.

23               THE WITNESS:  Correct, that's what they  
24   state.

1 BY MR. SLATER:

2 Q. Now, let's look at Exhibit PLT1096, which  
3 is the abstract that predated the published article.  
4 And in the abstract look at the conclusion --

5 MR. ISMAIL: Sorry. Objection, hearsay  
6 and this is not a material that Dr. Elliott  
7 disclosed. It's beyond the scope of his  
8 disclosure so it's improper.

9 MR. SLATER: Okay. Well, you brought it  
10 up.

11 MR. ISMAIL: No, I didn't actually, but go  
12 ahead. The objection is hearsay and improper  
13 disclosure of material.

14 BY MR. SLATER:

15 Q. Doctor, the conclusion to the abstract by  
16 Lowman about whether the Prolift® causes dyspareunia,  
17 just read for me the first sentence, please --

18 MR. ISMAIL: Objection, hearsay.

19 MR. SLATER: -- of the conclusion.

20 MR. ISMAIL: Improper disclosure.

21 THE WITNESS: The abstract which was  
22 presented at the --

23 BY MR. SLATER:

24 Q. I'm not -- Doctor, I'm talking about the



1 abstract I just handed to you.

2 A. Yeah, no, and I can say it was presented  
3 at the GYN surgeons meeting in 2008. Just so we're  
4 clear what I'm reading here, under conclusion, "The  
5 Prolift® procedure may be associated with a high (24%)  
6 de novo dyspareunia rate..."

7 Q. So when they presented it originally they  
8 said 24%, a high rate, and then when they published  
9 they went down to 16.7%?

10 MR. ISMAIL: Objection, leading, improper  
11 disclosure, hearsay.

12 THE WITNESS: That is correct.

13 BY MR. SLATER:

14 Q. And in the article if you turn to page e5?

15 A. Okay, I'm there.

16 Q. And in the center column, if you just read  
17 through it, they assess dyspareunia by two different  
18 methods, by a validated questionnaire versus a chart  
19 review.

20 MR. ISMAIL: Objection.

21 BY MR. SLATER:

22 Q. Do you see that?

23 MR. ISMAIL: I'm sorry. Objection,  
24 hearsay.

1 THE WITNESS: Yes, and a telephone  
2 interview.

3 BY MR. SLATER:

4 Q. And, ultimately, if you read through this  
5 they say they ultimately chose the chart review, which  
6 gave them the 16.7% rate instead of the validated  
7 questionnaires that they reported at 24%, didn't they?

8 MR. ISMAIL: Objection, leading and  
9 hearsay.

10 THE WITNESS: That's what they state in  
11 there, yes.

12 BY MR. SLATER:

13 Q. These validated questionnaires, these are  
14 validated through professional societies and academics  
15 and people who know a lot in this field; aren't they?

16 MR. ISMAIL: Objection, leading, hearsay.

17 THE WITNESS: That is correct, yes.

18 BY MR. SLATER:

19 Q. Okay. Now, you were asked a bunch of  
20 questions by counsel about the use of polypropylene to  
21 treat pelvic conditions, you remember he asked you  
22 about that, it's been used in a lot of products by  
23 different ways?

24 A. Correct.

1 Q. And he asked you about Bard Marlex; do you  
2 remember that?

3 A. Correct.

4 Q. Are you familiar with the Bard Avaulta?

5 A. Oh, yes.

6 MR. ISMAIL: Objection, beyond the scope.

7 I didn't ask him anything about Marlex.

8 MR. SLATER: You mentioned it.

9 MR. ISMAIL: No, I didn't. He did. He  
10 misunderstood my question.

11 THE WITNESS: No, I did not misunderstand.

12 I understood it, but I did bring it up.

13 BY MR. SLATER:

14 Q. Remember you were asked by counsel about  
15 Marlex and that that was one of the materials used to  
16 treat patients?

17 MR. ISMAIL: Objection, actually misstates  
18 the record, beyond the scope.

19 THE WITNESS: I remember the discussion.

20 BY MR. SLATER:

21 Q. You were asked about the use of mesh  
22 transvaginally?

23 A. Correct.

24 Q. All right. And one of the ways that's

1     done -- was done was by the Bard Avaulta, right?

2                     MR. ISMAIL:   Object, leading.

3                     THE WITNESS:   Correct.

4     BY MR. SLATER:

5                     Q.    And I've given you now the MSDS, the  
6     Material Safety Data Sheet, for the Marlex material in  
7     the Bard Avaulta and on the -- and you've seen this  
8     before, right?

9                     A.    Yes, I have.

10                    Q.    Marked as Plaintiff's Trial Exhibit P2402  
11    and if you look right on the front page -- let me start  
12    again.

13                    If you look on the front page of this Exhibit  
14    P2402, what does it say?  There is a medical  
15    application caution, what does that say?

16                    MR. ISMAIL:  Objection, hearsay, beyond  
17    the scope, not disclosed in this case by the  
18    witness.

19    BY MR. SLATER:

20                    Q.    What does that say?

21                    A.    It says "Medical Application Caution:  Do  
22    not use this Phillips Sumika Polypropylene Company  
23    material in medical application involving permanent  
24    implantation in the human body or permanent contact

1 with internal body fluids or tissues."

2 Q. And then what does it say in the next --

3 MR. ISMAIL: Objection --

4 BY MR. SLATER:

5 Q. -- paragraph?

6 MR. ISMAIL: I'm sorry. Objection, 403,  
7 hearsay, beyond the scope.

8 MR. SLATER: Sure.

9 BY MR. SLATER:

10 Q. Does it basically say that, again, don't  
11 use this polypropylene material in the human body for  
12 medical applications?

13 MR. ISMAIL: Same objections and now  
14 leading.

15 THE WITNESS: Yes, but it goes on saying  
16 "involving brief or temporary implantation in  
17 the human body."

18 BY MR. SLATER:

19 Q. Okay. And that's -- this is the  
20 polypropylene used in one of those mesh devices used  
21 transvaginally that counsel asked you about, correct?

22 MR. ISMAIL: Objection, leading, hearsay,  
23 403, beyond the scope.

24 THE WITNESS: It's one of the meshes used

1 in one of the products, yes.

2 BY MR. SLATER:

3 Q. Okay. Now, you were asked by counsel  
4 about conservative treatment of exposure erosion,  
5 remember that, counsel asked you a bunch of questions?

6 A. Yes, I do.

7 Q. Do you have handy or can you get handy  
8 PLT1095, it's the article by Heesakkers and Withagen.  
9 I actually have another copy of it here, if it will  
10 save time.

11 MR. ISMAIL: Which one?

12 MR. SLATER: It's the one I gave you at  
13 the start of the day today.

14 MR. ISMAIL: Thank you.

15 BY MR. SLATER:

16 Q. And what I want to do -- this is the  
17 article by that urologist that you said you knew from  
18 SUFU.

19 A. Yeah, John Heesakkers. Not from SUFU,  
20 from European Urology Association.

21 Q. Ah, sorry. And if we look now at Page  
22 1399 of this article which you already testified  
23 about --

24 MR. ISMAIL: Objection, hearsay, 403. I

1           didn't ask him about the article, you did.

2           So beyond the scope, 403, hearsay and this  
3           is the article that, as we pointed out before,  
4           was not disclosed by the witness before today.

5   BY MR. SLATER:

6           Q.   Okay. Doctor, during the  
7           cross-examination counsel asked you about the efficacy  
8           of using conservative treatments to treat mesh  
9           erosions; do you remember that?

10          A.   Correct.

11          Q.   And if we look at Page 1399 of this  
12          article, and you look at the left-hand column, first  
13          full paragraph it says, "Mesh-related complications  
14          were unsuccessfully treated conservatively with  
15          estrogen cream, antibiotics and/or physiotherapy prior  
16          to mesh excision in 63% of patients."

17          Is that significant --

18          MR. ISMAIL: Objection, hearsay --

19   BY MR. SLATER:

20          Q.   -- to you?

21          MR. ISMAIL: Sorry. Objection, hearsay,  
22          403, improper disclosure.

23          MR. SLATER: You have a standing objection  
24          for hearsay, counsel.

1 MR. ISMAIL: Okay. Thank you. I'm  
2 actually adding to the objection, but thank  
3 you. Did I get them all?

4 403, improper disclosure, beyond the  
5 scope. Thank you.

6 THE WITNESS: Yes, it's quite significant.

7 BY MR. SLATER:

8 Q. Why is that?

9 MR. ISMAIL: Same objections.

10 THE WITNESS: Traditionally, and if you  
11 look at what I answered in 2012 deposition, is  
12 that 50% of these mesh extrusions can be  
13 treated conservatively and that's it.

14 Researchers like this Dutch group, along  
15 with Abbott, are now saying that 50% of those  
16 which are treated conservatively ultimately go  
17 on to surgery, and this one actually says 63%,  
18 so it's actually a higher percent than Abbott,  
19 et.al.

20 BY MR. SLATER:

21 Q. Okay. Now, you were asked a bunch of  
22 questions by counsel about RCTs and how many studies  
23 there are of the Prolift®; do you remember that  
24 questioning?



1 A. Yes, I do.

2 MR. SPECTER: RCT.

3 BY MR. SLATER:

4 Q. Randomized controlled trials, right?

5 A. Correct.

6 Q. That's when they take a few different  
7 procedures and they compare them, basically.

8 A. A two-armed study, yes.

9 Q. Okay. And are you -- well, let me hand  
10 you this. This is going to be Exhibit 2503.

11 And this is a letter from the FDA to Mr. Brian  
12 Kanerviko, a worldwide director of regulatory at  
13 Ethicon.

14 You see this?

15 A. Yes, I do.

16 Q. Okay. And you are familiar -- are you  
17 familiar or not with the interaction between Ethicon  
18 and the FDA regarding the 522 studies?

19 A. Yes, I've read those.

20 Q. Okay. And what I'd like to do is to cut  
21 to the chase, let's turn to Page 4 of this letter.

22 MR. ISMAIL: Counsel, if you wouldn't mind  
23 giving me a second when you hand me an exhibit  
24 to see what it is.

1 I object to this exhibit as beyond the  
2 scope, 403, beyond the time period at issue in  
3 this case and potentially subject to a  
4 stipulation that you proposed.

5 BY MR. SLATER:

6 Q. In Paragraph 10 of this letter to the FDA  
7 I just want to read a little bit and then I'm going to  
8 ask you a few questions. It says, "For GYNECARE  
9 PROLIFT® Pelvic Floor Repair Systems, you provided 2  
10 published articles with the clinical data collected  
11 under two randomized controlled trials to satisfy the  
12 522 orders. However, these studies do not address  
13 several questions in the 522 order."

14 Do you see that?

15 A. Yes I do.

16 MR. ISMAIL: Same objections and also  
17 hearsay.

18 BY MR. SLATER:

19 Q. And just simply, the 522 orders were where  
20 the FDA wrote and told Ethicon you need to do some very  
21 high level studies in order to prove these are -- this  
22 is a safe product, the Prolift®?

23 MR. ISMAIL: Same objections and now with  
24 leading.

1 THE WITNESS: Right, it's a response  
2 saying there's an application and here's where  
3 we have concerns.

4 BY MR. SLATER:

5 Q. And the FDA talks about which two RCTs  
6 they're talking about and it's Withagen and Altman,  
7 correct?

8 MR. ISMAIL: Objection, leading, hearsay.  
9 403.

10 THE WITNESS: Yes.

11 BY MR. SLATER:

12 Q. Let me ask the question differently.

13 THE COURT REPORTER: One at a time,  
14 please.

15 BY MR. SLATER:

16 Q. Rephrase.

17 Which of the two articles, if you look in the  
18 body of these two bullet points that the FDA is  
19 describing that Ethicon had submitted to try to satisfy  
20 the 522?

21 MR. ISMAIL: Just let me make my  
22 objections noted which didn't get last time,  
23 because it was talked over.

24 Hearsay, 403, beyond the scope and

1           improper disclosure. Thank you.

2           THE WITNESS: Withagen, et.al. and Altman,  
3           et.al.

4   BY MR. SLATER:

5           Q. And according to this did the FDA accept  
6   those articles as satisfying the FDA's concerns and  
7   need for a 522 order, study?

8           MR. ISMAIL: Objection, hearsay, 403,  
9           beyond the scope and improper subject for  
10          expert testimony.

11   BY MR. SLATER:

12          Q. What did they say at the bottom of that  
13   section? It says "Based on these limitations ..."

14          MR. ISMAIL: Same objections.

15          THE WITNESS: To answer your question  
16          initially, no, they did not say it was  
17          satisfying. And then, "Based on these  
18          limitations, the publications provided are not  
19          adequate to satisfy the 522 order."

20   BY MR. SLATER:

21          Q. And now I'll hand you exhibit we marked as  
22   P2452 and this is a letter from the FDA to Brian  
23   Kanerviko, worldwide director regulatory in Ethicon,  
24   July 9, 2012.

1 And you've seen this before?

2 A. Yes.

3 Q. And it says in the letter that the FDA had  
4 completed its review of Ethicon's response to the 522  
5 order requesting that the study be suspended, and they  
6 say, "This request is based on the plan to discontinue  
7 manufacture and marketing of the device in the United  
8 States within 120 days of the date of your letter. We  
9 agree to your request and will place the 522 order on  
10 hold until September 7, 2012 with the following  
11 conditions:"

12 Is that what the letter says?

13 MR. ISMAIL: Objection, hearsay, 403,  
14 beyond the scope, subsequent remedial measure,  
15 improper subject of expert testimony.

16 THE WITNESS: That's what it states.

17 BY MR. SLATER:

18 Q. And the first condition there is "Cease  
19 marketing by September 7, 2012."

20 Is that what it says?

21 MR. ISMAIL: Please note the same  
22 objections.

23 THE WITNESS: That what it states.

24 BY MR. SLATER:

1 Q. And then just below the conditions, it  
2 says, "FDA reminds you that you are obligated, under  
3 Section 522 of the act, to complete a postmarket  
4 surveillance study of your device to address the issues  
5 cited in FDA's letter dated January 3, 2012.  
6 Accordingly, you must submit us new study plan to your  
7 PS study informing" -- meaning post market surveillance  
8 study -- "informing FDA if commercial distribution of  
9 your device begins."

10 Is that what the letter says?

11 MR. ISMAIL: Please note the same  
12 objections.

13 THE WITNESS: That's what it states, yes.

14 BY MR. SLATER:

15 Q. And is it consistent with your  
16 understanding that after Ethicon said they weren't  
17 going to do the 522 studies and withdraw the products,  
18 that they actually withdrew the Prolift® from the  
19 market and no longer sell it?

20 MR. ISMAIL: Objection, leading, 403,  
21 beyond the scope, subsequent remedial measure,  
22 lack of foundation.

23 THE WITNESS: Yes, it was --

24 MR. ISMAIL: Sorry. Improper subject for

1 expert testimony. Sorry, Doctor.

2 THE WITNESS: It was pulled from the  
3 market, yes.

4 MR. ISMAIL: Move to strike as  
5 nonresponsive.

6 MR. SLATER: No other questions.

7 BY MR. ISMAIL:

8 Q. Doctor, just briefly.

9 You were asked -- earlier I showed you your  
10 sworn testimony from 2012 and you indicated that 50% of  
11 mesh exposures can be treated conservatively, correct?

12 A. Correct.

13 Q. What was the date of the article that  
14 counsel showed you just now in response to that  
15 testimony, Exhibit 1095?

16 A. Looks like it was published in 2011.

17 Q. In the event counsel's question regarding  
18 the Altman study on redirect -- redirect is allowed, I  
19 have some follow-up on that provisionally.

20 You were asked to -- he provided you what he  
21 characterized as the data on dyspareunia between  
22 Prolift® surgery and the native tissue surgery in that  
23 study, correct?

24 A. Correct.

1 Q. And he gave you some data points where  
2 numerically the rate of dyspareunia was higher with  
3 Prolift®.

4 Do you recall that was the information he gave  
5 you?

6 A. That is correct.

7 Q. Do you recall from your own memory, sir,  
8 that the dyspareunia rate between Prolift® and native  
9 tissue surgery in that Altman study was not  
10 statistically significant?

11 A. In the Altman study?

12 Q. Yes.

13 A. I don't have the Altman study in front of  
14 me. If you are telling me it's statistically equal, I  
15 have no reason to doubt you.

16 Q. Okay. So let me ask it this way: When  
17 you were answering Mr. Slater's questions when he gave  
18 you data points regarding that study, you did not  
19 recall, from your own recollection, whether the data he  
20 was giving you was at all accurate, correct?

21 MR. SLATER: Objection. By the way, I  
22 just want to preserve my objections on this  
23 line of questioning.

24 THE WITNESS: With -- actually, I'm sorry,



1           could you repeat your question.

2       BY MR. ISMAIL:

3           Q.     Just so everything is clear as to where  
4     this is coming from, just now, a few minutes ago  
5     Mr. Slater represented to you certain data from a study  
6     known as Altman, correct?

7           A.     Correct.

8           Q.     He gave you the numbers from that study in  
9     his question, but would I be fair to assume you didn't  
10    recall them yourself?

11          A.     No, I -- no, you are correct, I don't  
12    recall them, but the Altman study has major issues  
13    that --

14          Q.     I didn't bring it up.

15                 MR. SLATER:  Don't interrupt him in the  
16    middle of the answer, please.  Let him finish.

17       BY MR. ISMAIL:

18          Q.     Doctor, I just want to make sure --

19                 MR. SLATER:  No, no, hang on, hang on, he  
20    was talking.  Let him finish.  He is going to  
21    finish.

22                 MR. ISMAIL:  Then I will move to strike  
23    and we try again.

24                 MR. SLATER:  That's fine but you should

1 let him finish his answer.

2 MR. ISMAIL: Okay, okay, calm down.

3 THE WITNESS: Point well-taken.

4 But as I mentioned earlier, the Altman  
5 studies have major ethical issues, which I  
6 questioned the data. But to answer your  
7 question, I do not recall off the top of my  
8 head those numbers.

9 MR. ISMAIL: Move to strike.

10 BY MR. ISMAIL:

11 Q. Doctor, quite simply, when Mr. Slater  
12 represented to you what the data were from the Altman  
13 study, you did not, and still as you sit here now, do  
14 not know whether that data he gave you was the true  
15 reported data from that study, correct?

16 A. I don't recall those specific numbers out  
17 of the hundreds of studies I read, no.

18 Q. That's fine, and I'm not -- withdrawn.

19 And as you sit here today you can't recall  
20 whether the rate of dyspareunia comparing Prolift® to  
21 native tissue repair in the Altman study, if there was  
22 a numerical difference, whether that was statistically  
23 significant or not, true?

24 A. As I recall it was not statistically

1 different.

2 Q. Okay. And so the proper interpretation of  
3 a study where there are comparison between one surgical  
4 treatment and another surgical treatment, if it's not  
5 statistically significant, the proper interpretation of  
6 that is you would say the study does not show a  
7 difference for that outcome, correct?

8 A. Yeah, the proper way to state it is there  
9 was a percentage difference but not a statistical  
10 difference.

11 Q. Right.

12 And when you say there is not a statistical  
13 difference, earlier when we were talking about  
14 statistical significance, that's a way researchers can  
15 assess whether the observed difference is real or due  
16 to chance, correct?

17 A. That is correct.

18 Q. And if there's no statistically  
19 significant difference, one would conclude that there  
20 is -- that any observed difference between the two  
21 groups of patients in this study is potentially due to  
22 chance, correct?

23 A. Correct, during the frame of -- time frame  
24 of that study, that is correct.

1           Q.    And in the Altman study, as you've just  
2 confirmed, where there's no statistically significant  
3 difference in the outcome of dyspareunia, the proper  
4 interpretation of that study is that the Altman study  
5 does not establish -- withdrawn.

6           The proper interpretation of the Altman study  
7 is that there was no statistical difference shown in  
8 the risk of dyspareunia comparing Prolift® to native  
9 tissue surgery, true?

10           MR. SLATER: Just for the record, I've  
11 clearly stated an objection to this whole line  
12 of questioning.

13           THE WITNESS: To answer your question, you  
14 are correct as it is stated in the document,  
15 with the reservations I've had as far as the --  
16 is it a true study.

17 BY MR. ISMAIL:

18           Q.    Okay. But as to the data that Mr. Slater  
19 gave you, it wasn't -- I didn't give you that data, he  
20 gave you that data, right?

21           A.    Correct.

22           Q.    And if you were going to interpret the  
23 data he gave you, where there was an absence of  
24 statistical significance, you would conclude the Altman

1 study does not show an increased risk of dyspareunia  
2 comparing Prolift® to native tissue surgery, true?

3 MR. SLATER: Same objection.

4 THE WITNESS: As I review any study, not  
5 just this, not just for this litigation, you  
6 have to look at the percentage, the true  
7 numbers and then the statistical significance  
8 and you cannot -- if they're statistically  
9 equal, then you have to state that  
10 statistically they were equal.

11 BY MR. ISMAIL:

12 Q. And that was true with respect to the risk  
13 of dyspareunia in the Altman study that Mr. Slater gave  
14 you just now, correct?

15 A. That is correct, yes.

16 MR. ISMAIL: Thank you. No further  
17 questions.

18 MR. SLATER: Just for the record, make it  
19 very clear, the questioning on Altman was  
20 conditional in case any of the vague  
21 questioning on cross-examination regarding  
22 studies, without establishing them as being  
23 authoritative, would be permitted in any way.

24 I have no other questions.

Daniel S. Elliott, M.D.

1 THE VIDEOGRAPHER: The time is 3:41 and  
2 this concludes the videotape deposition of  
3 Dr. Daniel Elliott.

4 (Witness excused.)

5 (Mr. Slater leaves the deposition room.)

6 MR. ISMAIL: We have requested the  
7 stenographic record note that the deposition  
8 remains open due to the instructions not to  
9 answer. Mr. Slater was advised but was outside  
10 the deposition room.

11 — — —

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## C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

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Margaret M. Reihl, RPR, CRR, CLR

CSR #XI01497 Notary Public

Daniel S. Elliott, M.D.

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